ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 053618 0027 Rev. 01

Manufacturer:

ZHERMACK S.p.A
Via Bovazecchino 100
45021 Badia Polesine (RO)
ITALY

Product Category(ies): **Disinfectants for Medical Devices; Acrylic Resins for Dentures**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 053618 0027 Rev. 01

Report No.: ITA1674407

Valid from: 2021-04-13
Valid until: 2024-03-19

Date, 2021-04-13

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Zhermack S.p.A.
Manufacturer address and contact details	Via Bovazecchino 100, 45021, Badia Polesine (RO), Italy Phone: +39 0425 597611 info@zhermack.com
Single Registration Number (SRN) (if available)	00594630295

Authorised Representative name (if applicable)	N/A
Authorised Representative address and contact details	N/A
Single Registration Number (SRN) (if available)	N/A

Notified body name (if applicable)	X See attached schedule
Notified body number (if applicable)	X See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Zhermack S.p.A.

Via Bovazecchino, 100
45021 Badia Polesine (RO) Italy
T +39 0425 597611 | F +39 0425 53596
www.zhermack.com | info@zhermack.com

C.F. e P.IVA IT00594630295
R.E.A. 86603 - R.I. RO 00594630295
M. RO 001381 - Isc. Reg. A.E.E. IT07111000002
Cap. Soc. € 1.032.000,00

Directive Certificate number(s) to which this confirmation is made (if applicable)	X See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	X See attached schedule
End date of extended validity/transition period	X See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[3]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

[3] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

Zhermack S.p.A.

Via Bovazecchino, 100
45021 Badia Polesine (RO) Italy
T +39 0425 597611 | F +39 0425 53596
www.zhermack.com | info@zhermack.com

C.F. e P.IVA IT00594630295
R.E.A. 86603 - R.I. RO 00594630295
M. RO 001381 - Isc. Reg. A.E.E. IT07111000002
Cap. Soc. € 1.032.000,00

of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

- ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
- ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

X Expired/expires *after* 20 March 2023:

Choose one applicable statement:

X Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

X Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

Zhermack S.p.A.

Via Bovazecchino, 100
45021 Badia Polesine (RO) Italy
T +39 0425 597611 | F +39 0425 53596
www.zhermack.com | info@zhermack.com

C.F. e P.IVA IT00594630295
R.E.A. 86603 - R.I. RO 00594630295
M. RO 001381 - Isc. Reg. A.E.E. IT07111000002
Cap. Soc. € 1.032.000,00

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

X A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: Zhermack S.p.A.

Location & Date: Badia Polesine, 11/01/2024

Signature, Print Name, Title _____

Barbara Baruzzo, Sr QA&RA Manager

Contact Details (at least email): barbara.baruzzo@zhermack.com

Zhermack S.p.A.

Zhermack S.p.A.

Via Bovazecchino, 100
45021 Badia Polesine (RO) Italy
T +39 0425 597611 | F +39 0425 53596
www.zhermack.com | info@zhermack.com

C.F. e P.IVA IT00594630295
R.E.A. 86603 - R.I. RO 00594630295
M. RO 001381 - Isc. Reg. A.E.E. IT07111000002
Cap. Soc. € 1.032.000,00

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

*Note: process to be achieved as per specified regulation 2023/607 due dates.

Identification of the device(s)[4] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number**(s) to which this confirmation is made (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
ACRYTEMP C700201	G1 053618 0027 Rev. 01	19/03/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123*	31/12/2028	N/A
ACRYTEMP C700200	G1 053618 0027 Rev. 01	19/03/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123*	31/12/2028	N/A
ACRYTEMP C700215	G1 053618 0027 Rev. 01	19/03/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123*	31/12/2028	N/A
ACRYTEMP C700205	G1 053618 0027 Rev. 01	19/03/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123*	31/12/2028	N/A
ACRYTEMP C700211	G1 053618 0027 Rev. 01	19/03/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123*	31/12/2028	N/A

[4] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Zhermack S.p.A.

Via Bovazecchino, 100
45021 Badia Polesine (RO) Italy
T +39 0425 597611 | F +39 0425 53596
www.zhermack.com | info@zhermack.com

C.F. e P.IVA IT00594630295
R.E.A. 86603 - R.I. RO 00594630295
M. RO 001381 - Isc. Reg. A.E.E. IT07111000002
Cap. Soc. € 1.032.000,00

ZETA 1 ULTRA C810000	G1 053618 0027 Rev. 01	19/03/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123*	31/12/2028	N/A
ZETA 2 SPOREX C810011	G1 053618 0027 Rev. 01	19/03/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123*	31/12/2028	N/A
ZETA 3 FOAM C810025	G1 053618 0027 Rev. 01	19/03/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123*	31/12/2028	N/A
ZETA 3 FOAM C810026	G1 053618 0027 Rev. 01	19/03/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123*	31/12/2028	N/A
ZETA 3 SOFT C810023	G1 053618 0027 Rev. 01	19/03/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123*	31/12/2028	N/A
ZETA 3 SOFT C810024	G1 053618 0027 Rev. 01	19/03/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123*	31/12/2028	N/A
ZETA 3 SOFT C810029	G1 053618 0027 Rev. 01	19/03/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123*	31/12/2028	N/A
ZETA 3 SOFT C810027	G1 053618 0027 Rev. 01	19/03/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123*	31/12/2028	N/A
ZETA 3 SOFT C810028	G1 053618 0027 Rev. 01	19/03/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123*	31/12/2028	N/A

Zhermack S.p.A.

Via Bovazecchino, 100
45021 Badia Polesine (RO) Italy
T +39 0425 597611 | F +39 0425 53596
www.zhermack.com | info@zhermack.com

C.F. e P.IVA IT00594630295
R.E.A. 86603 - R.I. RO 00594630295
M. RO 001381 - Isc. Reg. A.E.E. IT07111000002
Cap. Soc. € 1.032.000,00

ZETA 3 SOFT C810032	G1 053618 0027 Rev. 01	19/03/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123*	31/12/2028	N/A
ZETA 3 WIPES TOTAL C810062	G1 053618 0027 Rev. 01	19/03/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123*	31/12/2028	N/A
ZETA 3 WIPES TOTAL C810063	G1 053618 0027 Rev. 01	19/03/2024	TÜV SÜD Product Service GmbH 0123D	TÜV SÜD Product Service GmbH 0123*	31/12/2028	N/A
ZETA 5 POWER ACT C810040	G1 053618 0027 Rev. 01	19/03/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123*	31/12/2028	N/A
ZETA 7 SOLUTION C810048	G1 053618 0027 Rev. 01	19/03/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123*	31/12/2028	N/A
ZETA 7 SPRAY C810050	G1 053618 0027 Rev. 01	19/03/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123*	31/12/2028	N/A
HYDROCOLOR 5 C302120	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDROGUM 5 C302071	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDROGUM 5 C302075	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDROGUM 5	N/A	N/A	N/A	TÜV SÜD	31/12/2028	N/A

Zhermack S.p.A.

Via Bovazecchino, 100
45021 Badia Polesine (RO) Italy
T +39 0425 597611 | F +39 0425 53596
www.zhermack.com | info@zhermack.com

C.F. e P.IVA IT00594630295
R.E.A. 86603 - R.I. RO 00594630295
M. RO 001381 - Isc. Reg. A.E.E. IT07111000002
Cap. Soc. € 1.032.000,00

C302070				Product Service GmbH 0123		
HYDROGUM C302025	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDROGUM C302051	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
NEOCOLLOID C302205	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
ORTHOPRINT C302161	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
ORTHOPRINT C302145	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
ORTHOPRINT C302171	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
PINKALGIN 5 C302140	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
TROPICALGIN EXTRA FAST C302244	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
TROPICALGIN C302242	N/A	N/A	N/A	TÜV SÜD Product Service GmbH	31/12/2028	N/A

Zhermack S.p.A.

Via Bovazecchino, 100
45021 Badia Polesine (RO) Italy
T +39 0425 597611 | F +39 0425 53596
www.zhermack.com | info@zhermack.com

C.F. e P.IVA IT00594630295
R.E.A. 86603 - R.I. RO 00594630295
M. RO 001381 - Isc. Reg. A.E.E. IT07111000002
Cap. Soc. € 1.032.000,00

				0123		
TROPICALGIN C302240	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
TROPICALGIN C302245	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
TROPICALGIN NORMAL. C302241	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
ZETALGIN C301001	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
ZETALGIN CHROMATIC C301004	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
OCCLUFAST ROCK C200726	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
OCCLUFAST+ COLOR C200780	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
OCCLUFAST+ COLOR C200781	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
OCCLUFAST+ COLOR C200782	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A

Zhermack S.p.A.

Via Bovazecchino, 100
45021 Badia Polesine (RO) Italy
T +39 0425 597611 | F +39 0425 53596
www.zhermack.com | info@zhermack.com

C.F. e P.IVA IT00594630295
R.E.A. 86603 - R.I. RO 00594630295
M. RO 001381 - Isc. Reg. A.E.E. IT07111000002
Cap. Soc. € 1.032.000,00

OCCLUFAST+ C200790	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
OCCLUFAST+ C200791	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
OCCLUFAST+ C200792	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
OCCLUFAST CAD C200800	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
OCCLUFAST ROCK C203220	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
Elite Glass C401610	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
ELITE HD+ MONOPHASE NORMAL SET C202020	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
ELITE HD+ TRAY MATERIAL FAST SET C202032	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
ELITE HD+ MAXI MONOPHASE NORMAL SET C202300	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A

Zhermack S.p.A.

Via Bovazecchino, 100
45021 Badia Polesine (RO) Italy
T +39 0425 597611 | F +39 0425 53596
www.zhermack.com | info@zhermack.com

C.F. e P.IVA IT00594630295
R.E.A. 86603 - R.I. RO 00594630295
M. RO 001381 - Isc. Reg. A.E.E. IT07111000002
Cap. Soc. € 1.032.000,00

ELITE HD+ MAXI MONOPHASE NORMAL SET C202310	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
ELITE HD+ MAXI TRAY MATERIAL FAST SET C202320	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
ELITE HD+ MAXI TRAY MATERIAL FAST SET C202330	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
ELITE HD+ MAXI PUTTY SOFT NORMAL SET C202340	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
ELITE HD+ MAXI PUTTY SOFT NORMAL SET C202350	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
ELITE HD+ MAXI PUTTY SOFT FAST SET C202360	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
ELITE HD+ MAXI PUTTY SOFT FAST SET C202370	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
ELITE HD+ PUTTY SOFT NORMAL SET C203000	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
ELITE HD+ PUTTY SOFT NORMAL SET	N/A	N/A	N/A	TÜV SÜD Product Service GmbH	31/12/2028	N/A

Zhermack S.p.A.

Via Bovazecchino, 100
45021 Badia Polesine (RO) Italy
T +39 0425 597611 | F +39 0425 53596
www.zhermack.com | info@zhermack.com

C.F. e P.IVA IT00594630295
R.E.A. 86603 - R.I. RO 00594630295
M. RO 001381 - Isc. Reg. A.E.E. IT07111000002
Cap. Soc. € 1.032.000,00

C203002				0123		
ELITE HD+ PUTTY SOFT FAST SET C203010	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
ELITE HD+ PUTTY SOFT FAST SET C203012	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
ELITE HD+ REGULAR BODY NORMAL SET C203020	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
ELITE HD+ REGULAR BODY NORMAL SET C203025	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
ELITE HD+ LIGHT BODY NORMAL SET C203030	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
ELITE HD+ LIGHT BODY NORMAL SET C203035	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
ELITE HD+ LIGHT BODY FAST SET C203040	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
ELITE HD+ SUPER LIGHT BODY FAST SET C203050	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
ELITE HD+ LIGHT BODY FAST SET	N/A	N/A	N/A	TÜV SÜD	31/12/2028	N/A

Zhermack S.p.A.

Via Bovazecchino, 100
45021 Badia Polesine (RO) Italy
T +39 0425 597611 | F +39 0425 53596
www.zhermack.com | info@zhermack.com

C.F. e P.IVA IT00594630295
R.E.A. 86603 - R.I. RO 00594630295
M. RO 001381 - Isc. Reg. A.E.E. IT07111000002
Cap. Soc. € 1.032.000,00

C203090				Product Service GmbH 0123		
ELITE HD+ PUTTY SOFT FAST SET C203091	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
ELITE HD+ PUTTY SOFT NORMAL SET C203092	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
ELITE HD+ SPECIAL PACK C203127	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE LIGHT BODY NORMAL SET C207000	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE LIGHT BODY FAST SET C207001	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE EXTRA LIGHT BODY NORMAL SET C207002	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE EXTRA LIGHT BODY FAST SET C207003	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE REGULAR BODY NORMAL SET C207004	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A

Zhermack S.p.A.

Via Bovazecchino, 100
45021 Badia Polesine (RO) Italy
T +39 0425 597611 | F +39 0425 53596
www.zhermack.com | info@zhermack.com

C.F. e P.IVA IT00594630295
R.E.A. 86603 - R.I. RO 00594630295
M. RO 001381 - Isc. Reg. A.E.E. IT07111000002
Cap. Soc. € 1.032.000,00

HYDRORISE REGULAR BODY FAST SET C207005	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE MONOPHASE NORMAL SET C207006	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE MONOPHASE FAST SET C207007	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE HEAVY BODY NORMAL SET C207008	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE HEAVY BODY FAST SET C207009	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE PUTTY NORMAL SET C207010	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE PUTTY FAST SET C207011	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE PUTTY NORMAL SET C207012	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE PUTTY FAST SET C207013	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A

Zhermack S.p.A.

Via Bovazecchino, 100
45021 Badia Polesine (RO) Italy
T +39 0425 597611 | F +39 0425 53596
www.zhermack.com | info@zhermack.com

C.F. e P.IVA IT00594630295
R.E.A. 86603 - R.I. RO 00594630295
M. RO 001381 - Isc. Reg. A.E.E. IT07111000002
Cap. Soc. € 1.032.000,00

HYDRORISE MAXI MONOPHASE NORMAL SET C207040	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE MAXI MONOPHASE FAST SET C207041	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE MAXI HEAVY BODY NORMAL SET C207042	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE MAXI HEAVY BODY FAST SET C207043	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE MAXI PUTTY NORMAL SET C207044	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE MAXI PUTTY FAST SET C207045	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE MAXI HEAVY BODY FAST SET C207063	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE MAXI PUTTY FAST SET C207065	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A

Zhermack S.p.A.

Via Bovazecchino, 100
45021 Badia Polesine (RO) Italy
T +39 0425 597611 | F +39 0425 53596
www.zhermack.com | info@zhermack.com

C.F. e P.IVA IT00594630295
R.E.A. 86603 - R.I. RO 00594630295
M. RO 001381 - Isc. Reg. A.E.E. IT07111000002
Cap. Soc. € 1.032.000,00

HYDRORISE TRIAL KIT C207071	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE MINI KIT C207080	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE IMPLANT HEAVY BODY C207090	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE IMPLANT LIGHT BODY C207091	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE IMPLANT MEDIUM BODY C207092	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE IMPLANT KIT HEAVY/LIGHT C207095	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE IMPLANT MEDIUM BODY C207096	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE IMPLANT MEDIUM BODY C207122	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
HYDRORISE IMPLANT MEDIUM BODY C207126	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A

Zhermack S.p.A.

Via Bovazecchino, 100
45021 Badia Polesine (RO) Italy
T +39 0425 597611 | F +39 0425 53596
www.zhermack.com | info@zhermack.com

C.F. e P.IVA IT00594630295
R.E.A. 86603 - R.I. RO 00594630295
M. RO 001381 - Isc. Reg. A.E.E. IT07111000002
Cap. Soc. € 1.032.000,00

FREEALGIN MAXI EXTRA FAST C300105	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
FREEALGIN MAXI EXTRA FAST C300106	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A
FREEALGIN C300110	N/A	N/A	N/A	TÜV SÜD Product Service GmbH 0123	31/12/2028	N/A

Zhermack S.p.A.

Via Bovazecchino, 100
45021 Badia Polesine (RO) Italy
T +39 0425 597611 | F +39 0425 53596
www.zhermack.com | info@zhermack.com

C.F. e P.IVA IT00594630295
R.E.A. 86603 - R.I. RO 00594630295
M. RO 001381 - Isc. Reg. A.E.E. IT07111000002
Cap. Soc. € 1.032.000,00

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 053618 0027 Rev. 01

Manufacturer:

ZHERMACK S.p.A
Via Bovazecchino 100
45021 Badia Polesine (RO)
ITALY

Product Category(ies): **Disinfectants for Medical Devices; Acrylic Resins for Dentures**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 053618 0027 Rev. 01

Report No.: ITA1674407

Valid from: 2021-04-13
Valid until: 2024-03-19

Date, 2021-04-13

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Add value.
Inspire trust.

TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

ZHERMACK S.p.A
trading as ZK SPA
Via Bovazecchino 100
45021 BADIA POLESINE (RO)
ITALY

Your reference/letter of	Our reference/name	E-mail	Fax extension	Date	Page
053618	ITA200220002804	rachele.ruggeri@tuvsud	n/a	2024-05-13	1 of 5

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 053618 0029 Rev. 00

Reference: **ITA200220002804**
Zhermack S.P.A. trading as ZK SPA, trading as ZRK SPA, trading as ZAC SPA - Via Bovazecchino 100, I-45021 Badia Polesine (RO), Italy

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: **IT-MF-000011215**

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.

- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert: CL 053618 0029 Rev. 00

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-05-13.

TÜV SÜD Product Service GmbH
Medical and Health Services

Rachele Ruggeri
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

SIGN-ID 915202

Florian Grentzebach
Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 1 **C810000 - ZETA 1 ULTRA** **BUDI: 805600037Z0104B**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #1; G1 053618 0027 REV.01 NB#0123 - TÜV SÜD Product Service GmbH
Device 2 **C810011 - ZETA 2 SPOREX** **BUDI: 805600037Z0204E**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #1; G1 053618 0027 REV.01 NB#0123 - TÜV SÜD Product Service GmbH
Device 3 **C810023 - ZETA 3 SOFT** **BUDI: 805600037Z0304H**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #1; G1 053618 0027 REV.01 NB#0123 - TÜV SÜD Product Service GmbH
Device 4 **C810024 - ZETA 3 SOFT** **BUDI: 805600037Z0304H**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate #1; G1 053618 0027 REV.01 NB#0123 - TÜV SÜD Product Service GmbH

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 5 **C810025 - ZETA 3 FOAM** **BUDI: 805600037Z0314K**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #1; G1 053618 0027 REV.01 NB#0123 - TÜV SÜD Product Service GmbH
Device 6 **C810026 - ZETA 3 FOAM** **BUDI: 805600037Z0314K**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #1; G1 053618 0027 REV.01 NB#0123 - TÜV SÜD Product Service GmbH
Device 7 **C810027 - ZETA 3 SOFT** **BUDI: 805600037Z0304H**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #1; G1 053618 0027 REV.01 NB#0123 - TÜV SÜD Product Service GmbH
Device 8 **C810028 - ZETA 3 SOFT** **BUDI: 805600037Z0304H**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate #1; G1 053618 0027 REV.01 NB#0123 - TÜV SÜD Product Service GmbH

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 9 **C810029 - ZETA 3 SOFT** **BUDI: 805600037Z0304H**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #1; G1 053618 0027 REV.01 NB#0123 - TÜV SÜD Product Service GmbH
Device 10 **C810032 - ZETA 3 SOFT** **BUDI: 805600037Z0304H**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #1; G1 053618 0027 REV.01 NB#0123 - TÜV SÜD Product Service GmbH
Device 11 **C810040 - ZETA 5 POWER ACT** **BUDI: 805600037Z0504P**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #1; G1 053618 0027 REV.01 NB#0123 - TÜV SÜD Product Service GmbH
Device 12 **C810048 - ZETA 7 SOLUTION** **BUDI: 805600037Z0714X**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate #1; G1 053618 0027 REV.01 NB#0123 - TÜV SÜD Product Service GmbH

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 13 **C810050 - ZETA 7 SPRAY** **BUDI: 805600037Z0704V**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #1; G1 053618 0027 REV.01 NB#0123 - TÜV SÜD Product Service GmbH
Device 14 **C810062 - ZETA 3 WIPES TOTAL** **BUDI: 805600037Z0324M**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #1; G1 053618 0027 REV.01 NB#0123 - TÜV SÜD Product Service GmbH
Device 15 **C810063 - ZETA 3 WIPES TOTAL** **BUDI: 805600037Z0324M**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #1; G1 053618 0027 REV.01 NB#0123 - TÜV SÜD Product Service GmbH
Device 16 **C700200 - ACRYTEMP** **BUDI: 805600037ACR04N**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #1; G1 053618 0027 REV.01 NB#0123 - TÜV SÜD Product Service GmbH

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		
Device 17 **C700201 - ACRYTEMP** **BUDI: 805600037ACR04N**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #1; G1 053618 0027 REV.01 NB#0123 - TÜV SÜD Product Service GmbH
Device 18 **C700205- ACRYTEMP** **BUDI: 805600037ACR04N**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #1; G1 053618 0027 REV.01 NB#0123 - TÜV SÜD Product Service GmbH
Device 19 **C700211 - ACRYTEMP** **BUDI: 805600037ACR04N**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A	☒ Certification as follows: Certificate #1; G1 053618 0027 REV.01 NB#0123 - TÜV SÜD Product Service GmbH
Device 20 **C700215 - ACRYTEMP** **BUDI: 805600037ACR04N**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted)	☒ N/A	☒ Certification as follows: Certificate #1; G1 053618 0027 REV.01 NB#0123 - TÜV SÜD Product Service GmbH

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 21 **C302120 -HYDROCOLOR 5** **BUDI- 805600037ALG052**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 22 **C302071 - HYDROGUM 5** **BUDI - 805600037ALG052**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 23 **C302075 - HYDROGUM 5** **BUDI - 805600037ALG052**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 24 **C302070 - HYDROGUM 5**	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
BUDI - 805600037ALG052	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device		
Device 25 **C302025 - HYDROGUM** **BUDI - 805600037ALG052**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 26 **C302051- HYDROGUM** **BUDI - 805600037ALG052**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 27 **C302205 - NEOCOLLOID** **BUDI - 805600037ALG052**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device		
Device 28 **C302161 - ORTHOPRINT** **BUDI - 805600037ALG052**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 29 **C302145 - ORTHOPRINT** **BUDI - 805600037ALG052**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 30 **C302171 - ORTHOPRINT** **BUDI - 805600037ALG052**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 31 **C302140 - PINKALGIN 5**	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
BUDI - 805600037ALG052	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device		
Device 32 **C302244 - TROPICALGIN EXTRA FAST** **BUDI - 805600037ALG052**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 33 **C302242 - TROPICALGIN** **BUDI - 805600037ALG052**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 34 **C302240 - TROPICALGIN** **BUDI - 805600037ALG052**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device		
Device 35 **C302245 - TROPICALGIN** **BUDI - 805600037ALG052**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 36 **C302241 - TROPICALGIN NORMAL** **BUDI - 805600037ALG052**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 37 **C301001 - ZETALGIN** **BUDI - 805600037ALG052**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 38	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
C301004 - ZETALGIN CHROMATIC **BUDI - 805600037ALG052**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device		
Device 39 **B000220 - ZELGAN ADVANCED** **BUDI - 805600037ALG052**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 40 **C200726 - OCCLUFAST ROCK** **BUDI - 805600037BIT05Z**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 41 **C200780 - OCCLUFAST+ COLOR** **BUDI - 805600037BIT05Z**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device		
Device 42 **C200781 - OCCLUFAST+ COLOR** **BUDI - 805600037BIT05Z**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 43 **C200782 - OCCLUFAST+ COLOR** **BUDI - 805600037BIT05Z**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 44 **C2007900- OCCLUFAST+** **BUDI - 805600037BIT05Z**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 45	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
C2007901- OCCLUFAST+ BUDI - 805600037BIT05Z	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device		
Device 46 **C2007902- OCCLUFAST+ BUDI - 805600037BIT05Z**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 47 **C200800 - OCCLUFAST CAD BUDI - 805600037BIT05Z**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 48 **C203220 - OCCLUFAST ROCK BUDI - 805600037BIT05Z**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device		
Device 49 **C401610 - ELITE GLASS** **BUDI - 805600037MAT076**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 50 **C202020 - ELITE HD+ MONOPHASE NORMAL SET** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 51 **C202032 - ELITE HD+ TRAY MATERIAL FAST SET** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 52	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
C202300 - ELITE HD+ MAXI MONOPHASE NORMAL SET BUDI-805600037VPS0BD	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device		
Device 53 **C202310 - ELITE HD+ MAXI MONOPHASE NORMAL SET BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 54 **C202320 - ELITE HD+ MAXI TRAY MATERIAL FAST SET BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 55 **C202330- ELITE HD+ MAXI TRAY MATERIAL FAST SET BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device		
Device 56 **C202340 - ELITE HD+ MAXI PUTTY SOFT NORMAL SET BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 57 **C202360 - ELITE HD+ MAXI PUTTY SOFT FAST SET** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 58 **C202370 - ELITE HD+ MAXI PUTTY SOFT FAST SET** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 59	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
C203000 - ELITE HD+ PUTTY SOFT NORMAL SET **BUDI - 805600037VPS0BD**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device		
Device 60 **C203002 - ELITE HD+ PUTTY SOFT NORMAL SET** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 61 **C203010 - ELITE HD+ PUTTY SOFT FAST SET** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 62 **C203012 - ELITE HD+ PUTTY SOFT FAST SET** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device		
Device 63 **C203020 - ELITE HD+ REGULAR BODY NORMAL SET BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 64 **C203025 - ELITE HD+ REGULAR BODY NORMAL SET BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 65 **C203030 - ELITE HD+ LIGHT BODY NORMAL SET** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 66	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
C203035 - ELITE HD+ LIGHT BODY NORMAL SET **BUDI - 805600037VPS0BD**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device		
Device 67 **C203040 - ELITE HD+ LIGHT BODY FAST SET** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 68 **C203050 - ELITE HD+ SUPER LIGHT BODY FAST SET** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 69 **C203090 - ELITE HD+ LIGHT BODY FAST SET** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device		
Device 70 **C203091 - ELITE HD+ PUTTY SOFT FAST SET** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 71 **C203092 - ELITE HD+ PUTTY SOFT NORMAL SET** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 72 **C203127 - ELITE HD+ KIT** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 73	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
C207000 - HYDRORISE LIGHT BODY NORMAL SET **BUDI - 805600037VPS0BD**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device		
Device 74 **C207001 - HYDRORISE LIGHT BODY FAST SET** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 75 **C207002 - HYDRORISE EXTRA LIGHT BODY NORMAL SET BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 76 **C207003 - HYDRORISE EXTRA LIGHT BODY FAST SET** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device		
Device 77 **C207004 - HYDRORISE REGULAR BODY NORMAL SET BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 78 **C207005 - HYDRORISE REGULAR BODY FAST SET BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 79 **C207006 - HYDRORISE MONOPHASE NORMAL SET BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 80	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
C207007 - HYDRORISE MONOPHASE FAST SET BUDI - 805600037VPS0BD	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device		
Device 81 **C207008 - HYDRORISE HEAVY BODY NORMAL SET** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 82 **C207009 - HYDRORISE HEAVY BODY FAST SET** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 83 **C207010 - HYDRORISE PUTTY NORMAL SET** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device		
Device 84 **C207011 - HYDRORISE PUTTY FAST SET** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 85 **C207012 - HYDRORISE PUTTY NORMAL SET** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 86 **C207013 - HYDRORISE PUTTY FAST SET** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 87	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
C207040 - HYDRORISE MAXI MONOPHASE NORMAL SET BUDI - 805600037VPS0BD	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device		
Device 88 **C207041 - HYDRORISE MAXI MONOPHASE FAST SET BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 89 **C207042 - HYDRORISE MAXI HEAVY BODY NORMAL SET BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 90 **C207043 - HYDRORISE MAXI HEAVY BODY FAST SET BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device		
Device 91 **C207044 - HYDRORISE MAXI PUTTY NORMAL SET** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 92 **C207045 - HYDRORISE MAXI PUTTY FAST SET** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 93 **C207063 - HYDRORISE MAXI HEAVY BODY FAST SET BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 94	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
C207065 - HYDRORISE MAXI PUTTY FAST SET **BUDI - 805600037VPS0BD**	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device		
Device 95 **C207071 - HYDRORISE MINI KIT** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 96 **C207080 - MINI KIT HYDRORISE NORMAL SET** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 97 **C207090 - HYDRORISE IMPLANT HEAVY BODY** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device		
Device 98 **C207091 - HYDRORISE IMPLANT LIGHT BODY** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 99 **C207092 - HYDRORISE IMPLANT MEDIUM BODY BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 100 **C207095 - HYDRORISE IMPLANT KIT HEAVY/LIGHT** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 101	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
C207096 - HYDRORISE IMPLANT MEDIUM BODY BUDI - 805600037VPS0BD	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device		
Device 102 **C207122 - HYDRORISE IMPLANT MEDIUM BODY BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 103 **C207126 - HYDRORISE IMPLANT MEDIUM BODY BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 104 **C300105 - FREEALGIN MAXI EXTRA FAST** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device		
Device 105 **C300106 - FREEALGIN MAXI EXTRA FAST** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 106 **C300110 - FREEALGIN** **BUDI - 805600037VPS0BD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives
Device 107 **DT22010 - ELITE ZA-OT 38** **BUDI - 805600037ZOT0C7**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class I reusable surgical instruments ☐ Class III implantable custom-made-device	☒ N/A	☒ N/A - Device did not require a Notified Body certificate under Directives

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-05-13	713221363 Rev. 00	Initial issue