bioloren
metal free dental system

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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	Bioloren S.r.l.
Manufacturer address and contact details	Via Alessandro Volta, 59 – 21047 Saronno (Va) - Italy
Single Registration Number (SRN) (if available)	IT-MF-000010816

Authorised Representative name (if applicable)	Not applicabile
Authorised Representative address and contact details	Not applicabile
Single Registration Number (SRN) (if available)	Not applicabile

Notified body name (if applicable)	Certiquality S.r.l.
Notified body number (if applicable)	0546
Directive Certificate number(s) to which this confirmation is made (if applicable)	Directive 93/42 Certificate number: 29691 Directive 93/42 Certificate number: 15168/2
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26/05/2024
End date of extended validity/transition period	31/12/2028

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]

[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.

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- 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 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.

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[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

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☐ 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:

☐ 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.

➢ **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:

Bioloren S.r.l.

Saronno, 17/05/2024

Umberto Ratti, Legal Representative

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Schedule of Devices

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

Identification of the device(s)[3] (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)
Posts WPCY 08/10/12/14/17/20 CPCY 08/10/12/14/17/20 TPCY 08/10/12/14/17/20 WPCY 40 CPCY 40 TPCY 40 WPCO 2 08/10/12/14 CPCO 2 08/10/12/14 TPCO 2 08/10/12/14 WPCO 2 40 CPCO 2 40 TPCO 2 40 WPCO 2-4 12/14/16/18 CPCO 2-4 12/14/16/18 TPCO 2-4 12/14/16/18 WPCO 2-4 40 TPCO 2-4 40 CPCO 2-4 40 WPCO 4-6 15/17/19/21 CPCO 4-6 15/17/19/21 TPCO 4-6 15/17/19/21 WPCO 4-6 40 TPCO 4-6 40 CPCO 4-6 40 WPCORET 10/12/14/16/18 CPCORET 10/12/14/16/18 WPCORET 40 CPCORET 40 TPCO GR 08/10/12/14 TPCO GR 40 WP CLR CO 08/10/12/14 TP CLR CO 08/10/12/14 WP CLR CO 40 TP CLR CO 40 WP OV 15/17/19 TP OV 15/17/19 MONOCORE S MONOCORE L MONOCORE POST BALL SMALL POST BALL LARGE / KIT POST BALL FIT / ADAPT 451808/451110/451212/451414/451717 450812T/451014T/451216T/451418T 450808/450110/450212/450414/450717	Directive 93/42 Certificate number: 29691	26/05/2024	Certiquality S.r.l. CE number 0546	IMQ S.p.A. CE number 0051	31/12/2028	Not applicable

[3] 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)

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456001/456002/456003/456000/455001456004						
PLT2CO 08/10/12/14						
PLCCY 08/10/12/14/17/20						
PLVCY 08/10/12/14/17/20						
PLRET2COT 08/10/12/14						
S180/S181/S182/S183/S184						
S170/S171/S172/S173/S174						
S190/S191/S192/S193						
NAUTVCY 08/10/12/14/17/20						
NAUTCCY 08/10/12/14/17/20						
NAUTRAV 08/10/12/14/16/18						
NAUTRAC 08/10/12/14/16/18						
RSP 001 / RSP 002						
PCYT08 /10 /12 /14						
PCYC08/10/12/14						
PCYTKIT / PCYCKIT						
PCONS/M/L						
P40T-008/P40T-01/P40T-12/P40T 14/P40T-16						
P40-008/P40-01/P40-12/P40-14/P40-16/P40-18						
P40-08C2/P40-01C2/P40-12C2/P40-14C2						
P40T-08C2/P40T-01C2/P40T-12C2/P40T-14C2						
P40-T55C6/P40-T65C6/P40-T75C6						
P40-55C6/P40-65C6/P40-75C6						
06110BC/06112BC/06114BC/06116BC/06118BC						
06110FC/06112FC/06114FC/06116FC/06118FC						
06008W/06010W/06012W/06014W/06017W/06020W						
06008B/06010B/06012B/06014B/06017B/06020B						
FFPVC08/10/12/14/17/20						
SPCC08/10/12/14/17/20						
PB18/PB25						
N° 1/2/3/4						
KIT 1 2 3 4						
77002/77003/77004/77005						
A-060001						
A060002/A-060003/A-060004/A-0005						
8800-100						
8800-401/8800-402/8800-403/8800-404/8800-405						
8800-201/8800-202/8800-203/8800-204/8800-205						
8800-101/8800-102/8800-103/8800-104/8800-105						
NORPOSCOR 08/10/12/14/NORPOSCORKIT						
7791/7792/7793/7794/7746/7747/7748/7749/7796/7797/ 7798/7799/7790/7745/7795						
BD81001/BD81002/BD81003/BD81004						
702421/702422/702423/702424/702425/702426/702420						
702431/702432/702433/702434/702435/702436/702430						
FGPVCY10/12/14/16						
FGTPCY10/12/14/16						
FCPCY10/12/14/16						
FGTOVPCY15/17/19						
FGTPKITCY						
FCPKITCY						
FGTPOVKIT						
RTP2CO 08/10/12/14						
RTOV 15/17/19						
RTPKIT2CO						
DIWP2CO 08/10/12/14						
PWP2CO 08/10/12/14						
PKITCO2W						
DWP2CO 08/10/12/14						
DTPCY 08/10/12/14						
DWPKIT2CO						
DTPKITCY						
MTPKIT2CO						
MTPKITCY						
MWPKITCYPF						
MWPKITCOPF						
MWPKITCY						
MWPKITCO						
MTPKIT2CO						
MTPKIT2COCLR						

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MTPKITCY MWPOV 15/17/19 MTPOV 15/17/19 MWP24CO 05/07/09/11 MWP46CO 08/10/12/14 MTPRET 08/10/12/14 MWPCY 08/10/12/14/16 MTPCY 08/10/12/14/16 MCPCY 08/10/12/14/16 MTP2COCLR 08/10/12/014 MWP2COCLR 08/10/12/014 **InFibra Ribbons** IF1T / IF1 / IF2 / IF3 / IF4 / IF25/IFKIT5 FC1 / FC2 / FC3 / FC4 BSM 1 / 2 / 3 / 4 200-5410 / 200-5411 / 200-5412 / 200-5413 / 2005414 / 200-5425 / 200-5400 FL1/2/3/4 454002 / 454003 / 454004 FN1 / FN2 / FN3 / FN4 GK1 GK2 GK3 GK4 7741 / 7742 / 7743 / 7744 / 7729						
Trilor (discs, blocks and arches) FDS 10/12/14/16/18/20/25 45FDS 10/12/14/16/18/20/25 FDZ 14/16/18/20/25 45FDZ 14/16/18/20/25 FDA 14/16/18/20/25 FDS 10/12/14/16/18/20/25 PK FDZ 14/16/18/20/25 PK TA 3.5 / 5.5 / 7.5 / TA KIT TA 3.5 / 5.5 / 7.5 PK / TA KIT PK TA 3.5 / 5.5 / 7.5 NW TA 3.5 / 5.5 / 7.5 NW PK FBS 201514 / 201915 / 401915 / 551915 / 652522 / 654022 / 554022 / 854022 45FB03401915 / 45FB07654022 / 45FB04551915 / 45FB08854022 / 45FB01201514 / 45FB02201915 / 45FB006652522 / 45FB05554022 FBK FBR	Directive 93/42 Certificate number 15168/2	26/05/2024	Certiquality S.r.l. CE number 0546	IMQ S.p.A. CE number 0051	31/12/2028	Not applicable