

RESORBA Medical GmbH
Am Flachmoor 16
Nuremberg
90475
Germany

09 April 2024

Notified Body Confirmation Letter
Reference: EU2023-607/656000 Rev 1

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 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has 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 following manufacturer:

RESORBA Medical GmbH
Am Flachmoor 16
Nuremberg
90475
Germany
SRN Number: DE-MF-000009480

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 the NB 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 the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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, by the 20 Mar 2023 for the relevant devices.

The transition timelines 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 (as amended by (EU) 2023/607), 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 excluding Well-established technologies (WET - 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 or have a 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)

On behalf of BSI Group The Netherlands B.V.,



Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB 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 at the pre-application stage)	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
N/A	N/A	N/A	N/A

Table 2: Devices covered by this letter and for which the NB 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 at the pre-application stage)	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
<p>PARASORB® Cone</p> <p>Listed on MDD Certificate as: "PARASORB® Cone Sterile haemostatic collagen cone Sizes: Diameter: 1.2, Height: 1.6"</p> <p>Also known as "SeptoCone"</p>	Class III	N/A	<p>Full Quality Assurance System Certificate for Collagen Products: 1434-MDD-193/2021, Expires 30 January 2024, NB 1434</p> <p>EC Design Examination Certificate for Collagen products: 1434-MDD-192/2021, Expires 30 January 2024, NB 1434</p>
<p>PARASORB® Fleece HD</p> <p>Listed on MDD Certificate as: "PARASORB® Fleece HD Sterile haemostatic collagen foam Sizes: 1.8 x 3.6, 7.0 x 3.0"</p>	Class III	N/A	<p>Full Quality Assurance System Certificate for Collagen Products: 1434-MDD-193/2021, Expires 30 January 2024, NB 1434</p> <p>EC Design Examination Certificate for Collagen products: 1434-MDD-192/2021, Expires 30 January 2024, NB 1434</p>
<p>PARASORB® Fleece</p> <p>Listed on MDD Certificate as: "PARASORB® Fleece Sterile haemostatic collagen foam</p>	Class III	N/A	<p>Full Quality Assurance System Certificate for Collagen Products: 1434-MDD-193/2021, Expires 30 January 2024, NB 1434</p>

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
Sizes: 1.8 x 3.6, 7.0 x 3.0"			EC Design Examination Certificate for Collagen products: 1434-MDD-192/2021, Expires 30 January 2024, NB 1434
KOLLAGEN resorb™ Listed on MDD Certificate as: "Kollagen resorb™" Sterile haemostatic collagen foam Sizes: 1.8 x 3.6, 7.0 x 3.0, 9.0 x 7.0, 12.0 x 9.0"	Class III	N/A	Full Quality Assurance System Certificate for Collagen Products: 1434-MDD-193/2021, Expires 30 January 2024, NB 1434 EC Design Examination Certificate for Collagen products: 1434-MDD-192/2021, Expires 30 January 2024, NB 1434
PARASORB RESODONT® Listed on MDD Certificate as: "PARASORB RESODONT®" Sterile haemostatic collagen membrane Sizes: 2.2 x 2.5, 3.2 x 2.5, 6.4 x 2.5"	Class III	N/A	Full Quality Assurance System Certificate for Collagen Products: 1434-MDD-193/2021, Expires 30 January 2024, NB 1434 EC Design Examination Certificate for Collagen products: 1434-MDD-192/2021, Expires 30 January 2024, NB 1434
PARASORB RESODONT® Forte Listed on MDD Certificate as: "PARASORB RESODONT® Forte" Sterile haemostatic collagen membrane Sizes: 1.6 x 2.5, 2.2 x 2.5, 3.2 x 2.5, 6.4 x 2.5"	Class III	N/A	Full Quality Assurance System Certificate for Collagen Products: 1434-MDD-193/2021, Expires 30 January 2024, NB 1434 EC Design Examination Certificate for Collagen products: 1434-MDD-192/2021, Expires 30 January 2024, NB 1434

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
RESODURA® Listed on MDD Certificate as: "RESODURA® Sizes: 2.5 x 2.5, 2.5 x 10.0, 5.0 x 5.0, , 5.0 x 10.0, 7.5 x 7.5, 10.0 x 10.0"	Class III	N/A	Full Quality Assurance System for Absorbable neurosurgical and spinal procedure collagen product: 1434-MDD-266/2020, Expires 13 February 2024, NB 1434 EC Design Examination for Absorbable neurosurgical and spinal procedure collagen product: 1434-MDD-265/2020, Expires 13 February 2024, NB 1434
GENTA-COLL® resorb Listed on MDD Certificate as: "GENTA-COLL resorb® Sizes: 2.5 x 2.5, 5.0 x 5.0, 10.0 x 10.0, 5.0 x 20.0" Also known as "GENTA-PROTEC®"	Class III	N/A	Full Quality Assurance System Certificate for Collagen Products with Gentamicin: 1434-MDD-277/2020, Expires 30 January 2024, NB 1434 EC Design Examination Certificate for Collagen products with Gentamicin: 1434-MDD-276/2020 (CE), Expires 30 January 2024, NB 1434
PARASORB® Cone Genta Listed on MDD Certificate as: "PARASORB® Cone Genta Size 1.2 x 1.6"	Class III	N/A	Full Quality Assurance System Certificate for Collagen Products with Gentamicin: 1434-MDD-264/2020, Expires 07 March 2024, NB 1434 EC Design Examination for Collagen products with Gentamicin: 1434-MDD-263/2020 (CE), Expires 07 March 2024, NB 1434
GENTA-FOIL resorb® Listed on MDD Certificate as: "GENTA-FOIL resorb® Sizes 2.5 x 2.5, 2.5 x 5.0, 10.0 x 10.0"	Class III	N/A	Full Quality Assurance System Certificate for Collagen Products with Gentamicin: 1434-MDD-264/2020, Expires 07 March 2024, NB 1434 EC Design Examination Certificate for Collagen products with Gentamicin: 1434-MDD-263/2020 (CE), Expires 07 March 2024, NB 1434

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
<p>Glycolon[®], Glycolon Oral[®],</p> <p>Listed on MDD Certificate as: "Suture Products, Copolymer Polyglycolic Acid and Caprolactone, monofil</p> <ul style="list-style-type: none"> - GLYCOLON[®] - GLYCOLON[®] ORAL - MONOGLYC <p>Also known as "MONOGLYC[™]"</p>	Class III	N/A	<p>EC Full Quality Assurance Certificate HD 60130909 0001, Expires 15 July 2023, NB 0197</p> <p>EC Design-Examination Certificate ID 60134978 0001, Expires 11 December 2023, NB 0197</p>
<p>PGA Resorba[®]</p> <p>Listed on MDD Certificate as: "Suture Products, polyglycolic acid, multifil-PGA RESORBA[®]"</p>	Class III	N/A	<p>EC Full Quality Assurance Certificate HD 60130909 0001, Expires 15 July 2023, NB 0197</p> <p>EC Design-Examination Certificate ID 60133798 0001, Expires 12 November 2023, NB 0197</p>
<p>Nylon</p> <p>Listed on MDD Certificate as: "Non-absorbable surgical suture products: Polyamide, monofil"</p>	Class IIb excluding Class IIb implantable non-WET	N/A	<p>EC Full Quality Assurance Certificate HD 60130909 0001, Expires 15 July 2023, NB 0197</p>
<p>Resolon[®]</p> <p>Listed on MDD Certificate as: "Non-absorbable surgical suture products: Polyamide, monofil"</p>	Class IIb excluding Class IIb implantable non-WET	N/A	<p>EC Full Quality Assurance Certificate HD 60130909 0001, Expires 15 July 2023, NB 0197</p>
<p>Supramid (Generic Device Group: Polyamide, psuedo/ monofilament, non-absorbable suture)</p> <p>Listed on MDD Certificate as: "Non-absorbable surgical suture products: Polyamide, monofil"</p>	Class IIb excluding Class IIb implantable non-WET	N/A	<p>EC Full Quality Assurance Certificate HD 60130909 0001, Expires 15 July 2023, NB 0197</p>

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
Supramid Oral (Generic Device Group: Polyamide, psuedo/monofilament, non-absorbable suture) Listed on MDD Certificate as: "Non-absorbable surgical suture products: Polyamide, monofil"	Class IIb excluding Class IIb implantable non-WET	N/A	EC Full Quality Assurance Certificate HD 60130909 0001, Expires 15 July 2023, NB 0197
RESOTEX® ORAL (Generic Device Group: Polyamide, psuedo/monofilament, non-absorbable suture) Listed on MDD Certificate as: "Non-absorbable surgical suture products: Polyamide, monofil"	Class IIb excluding Class IIb implantable non-WET	N/A	EC Full Quality Assurance Certificate HD 60130909 0001, Expires 15 July 2023, NB 0197
Moplylen Listed on MDD Certificate as "Non-absorbable surgical suture products: Polypropylene, monofil"	Class IIb excluding Class IIb implantable non-WET	N/A	EC Full Quality Assurance Certificate HD 60130909 0001, Expires 15 July 2023, NB 0197
Polyester (Generic Device Group: Polyester, multifilament, non-absorbable suture) Listed on MDD Certificate as: "Non-absorbable surgical suture products: Polyester, multifil"	Class IIb excluding Class IIb implantable non-WET	N/A	EC Full Quality Assurance Certificate HD 60130909 0001, Expires 15 July 2023, NB 0197
Supolene (Generic Device Group: Polyester, multifilament, non-absorbable suture) Listed on MDD Certificate as: "Non-absorbable surgical suture products: Polyester, multifil"	Class IIb excluding Class IIb implantable non-WET	N/A	EC Full Quality Assurance Certificate HD 60130909 0001, Expires 15 July 2023, NB 0197
ResoLOOPS™	Class IIa	N/A	EC Full Quality Assurance Certificate HD 60130909

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Listed on MDD Certificate as: "Other products for wound care: Retainers, Visceral"			0001, Expires 15 July 2023, NB 0197
Resopren Listed on MDD Certificate as: "Non-absorbable surgical suture products: PVDF, monofil"	Class IIb excluding Class IIb implantable non-WET	N/A	EC Full Quality Assurance Certificate HD 60130909 0001, Expires 15 July 2023, NB 0197
Seide/ Silk (Generic Device Group: Silk, multifilament, non-absorbable suture) Listed on MDD Certificate as: "Non-absorbable surgical suture products: Silk, multifil"	Class IIb excluding Class IIb implantable non-WET	N/A	EC Full Quality Assurance Certificate HD 60130909 0001, Expires 15 July 2023, NB 0197
STAHLDRAHT/ Steel (Generic Device Group: Steel, monofilament, non-absorbable suture) Listed on MDD Certificate as: "Non-absorbable surgical suture products: Steel, monofil and multifil"	Class IIb excluding Class IIb implantable non-WET	N/A	EC Full Quality Assurance Certificate HD 60130909 0001, Expires 15 July 2023, NB 0197
CAPROLON® Listed on MDD Certificate as: "Synthetic, Absorbable Suture Products CAPROLON®"	Class III	N/A	EC Full Quality Assurance Certificate CE 1434-MDD-354/2019, Expires 02 July 2024, NB 1434 EC Design-Examination Certificate CE 1434-MDD-353/2019, 02 July 2024, NB 1434

Confirmation Letter Revision History

Date	Action
2023/11/23	Initial issue

Date	Action
2024/04/08	Revision to add "Caprolon" and additional brand names under MDR application for "PARASORB® Cone", "GENTA-COLL® resorb" and "Glycolon®"
N/A	N/A

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