Geuder
Germany

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	Geuder AG
Manufacturer address and contact details	Hertzstraße 4 69126 Heidelberg Jens Widmann JWidmann@geuder.de +49 6221 306 754
Single Registration Number (SRN) (if available)	DE-MF-000008044

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

Notified body name (if applicable)	BSI Group The Netherlands B.V.
Notified body number (if applicable)	2797
Directive Certificate number(s) to which this confirmation is made (if applicable)	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.

Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	See attached schedule
End date of extended validity/transition period	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:

➢ **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

[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

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.

☒ Expired/expires *after* 20 March 2023:

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 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:

☒ 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.

☒ 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.

Geuder
Germany

Signed for and on behalf of the manufacturer:

Geuder AG, Heidelberg, 2024-03-14

Julius Müller-Albinus, CTO/CSO

Volker Geuder, PRRC

GEUDER AG
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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)
Ultrasonic Handpieces	CE 575415	2024-05-25	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Single-use Silicone Implants, Sterile	CE 575415	2024-05-25	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2027-12-31	Not applicable
Single-use Light Conductors / Fiber Optics, sterile, incl. Uno Colorline	CE 575415	2024-05-25	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Single-use Accessory Kits with Ultrasonic Tips, sterile	CE 575415	2024-05-25	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	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)

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)
Ultrasonic tips, reusable	CE 575415	2024-05-25	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Single-use Vitrectomy Instruments Uno Colorline, sterile	CE 575415	2024-05-25	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Single-use DMEK Cartridge, sterile	CE 575415	2024-05-25	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Single-use DMEK Transportation Cartridge, RAPID	CE 575415	2024-05-25	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Single-use Trocar System Uno Colorline, sterile	CE 575415	2024-05-25	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Single-use Ophthalmic Cannula	CE 575415	2024-05-25	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Injection/Infusion Tubing	CE 575415	2024-05-25	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable

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Single-use Tubing Sets, sterile	CE 575415	2024-05-25	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Tubing Sets, reusable	CE 575415	2024-05-25	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Cassettes	CE 575415	2024-05-25	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Single-use Vitrectors, sterile, Uno Colorline	CE 575415	2024-05-25	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
OcuLED Single-use LED Lightsource, sterile	CE 575415	2024-05-25	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Single-use Adapters, sterile	CE 575415	2024-05-25	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
I/A Instruments, sterile	CE 575415	2024-05-25	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable

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Megatron S4 and Megatron S4 HPS surgical systems (incl. G-30543 foot switch)	CE 711663	2024-05-26	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Endotron 532nm surgical system (incl. G-61101 foot switch)	CE 711664	2024-05-26	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Diathermy Instruments	CE 711665	2024-05-26	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Single-use Ophthalmic Cannula, sterile	CE 575413	2024-05-25	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Single-use Tubing Sets, sterile	CE 575413	2024-05-25	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Irrigation/Aspiration (I/A) Instruments, sterile	CE 575413	2024-05-25	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Single-use Endoprobes Uno Colorline, sterile	CE 575413	2024-05-25	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable

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Single-use Knives, sterile	CE 575413	2024-05-25	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Single-use Trephines, sterile	CE 575413	2024-05-25	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Bonn Injection Set, sterile	CE 575413	2024-05-25	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Measuring Instruments	CE 575413	2024-05-25	BSI Group The Netherlands B.V. 2797	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Diamond Knifes	Not applicable	Not applicable	Not applicable	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Injectors	Not applicable	Not applicable	Not applicable	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Clamps	Not applicable	Not applicable	Not applicable	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable

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Curettes and Spoons	Not applicable	Not applicable	Not applicable	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Lances and Knives	Not applicable	Not applicable	Not applicable	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Manipulators	Not applicable	Not applicable	Not applicable	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Forceps	Not applicable	Not applicable	Not applicable	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Retractors	Not applicable	Not applicable	Not applicable	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Scissors	Not applicable	Not applicable	Not applicable	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable

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Probes	Not applicable	Not applicable	Not applicable	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Punches	Not applicable	Not applicable	Not applicable	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Trephines	Not applicable	Not applicable	Not applicable	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Irrigation and Aspiration Instruments	Not applicable	Not applicable	Not applicable	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Fixation Rings	Not applicable	Not applicable	Not applicable	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Specula	Not applicable	Not applicable	Not applicable	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Localizers	Not applicable	Not applicable	Not applicable	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable

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Markers	Not applicable	Not applicable	Not applicable	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Needle Holders	Not applicable	Not applicable	Not applicable	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Razor Blade Holders	Not applicable	Not applicable	Not applicable	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable
Cleaning Adapters	Not applicable	Not applicable	Not applicable	BSI Group The Netherlands B.V. 2797	2028-12-31	Not applicable