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*
- 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	P.J. Dahlhausen & Co. GmbH
Manufacturer address and contact details	Emil-Hoffman-Str. 53 – 50996 Cologne/ Germany
Single Registration Number (SRN)	DE-MF-000006357

Notified body name	TÜV Product Service GmbH
Notified body number	0123
Directive Certificate number(s) to which this confirmation is made	☒ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	☒ See attached schedule
End date of extended validity/transition period	☒ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the listed **Directive Certificate** (see attached schedule) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- 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:

P. J. Dahlhausen & Co. GmbH • Emil-Hoffmann-Str. 53 • 50996 Köln • Germany
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- **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covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

    Expired/expires *after* 20 March 2023:

    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.

- **Quality Management System (QMS)**

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

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

  - The device(s) continue to comply with the 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:	P.J. Dahlhausen & Co GmbH
Location:	Emil-Hoffman-Str. 53, 50996 Cologne, Germany
Contact Details:	petra.hardt@dahlhausen.de

14.03.2024

P. Hardt

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Petra Hardt

Manager QM/RA

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Schedule of Devices

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

Identification of the device(s)	Directive Certificate number(s) to which this confirmation is made	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/contract signed	End date of extended validity / transition period
Sterile Guedel airways	G2S 015692 0504 Rev. 01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Sterile video camera drapes	G2S 015692 0504 Rev. 01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Sterile examination gloves	G2S 015692 0504 Rev. 01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Sterile catheter kits	G2S 015692 0504 Rev. 01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Sterile suture removal kits	G2S 015692 0504 Rev. 01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Sterile urine drainage bags	G2S 015692 0504 Rev. 01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Sterile infusion accessories	G2S 015692 0504 Rev. 01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Sterile Remover for skin stapler	G2S 015692 0504 Rev. 01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Sterile cover for surgical light handle	G2S 015692 0504 Rev. 01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Sterile umbilical cord clamp	G2S 015692 0504 Rev. 01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Sterile suction connecting tube	G2S 015692 0504 Rev. 01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028

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Sterile reservoir	G2S 015692 0504 Rev. 01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Sterile stitch cutter for external use	G2S 015692 0504 Rev. 01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Sterile thorax drainage system	G2S 015692 0504 Rev. 01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Sterile irrigation system	G2S 015692 0504 Rev. 01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Sterile bag for irrigation system	G2S 015692 0504 Rev. 01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Sterile thoracic drainage secretion bag	G2S 015692 0504 Rev. 01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Sterile protection cover for ultrasound sensors	G2S 015692 0504 Rev. 01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Filters	G1 015692 0502 Rev.01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Sterile transfusion devices	G1 015692 0502 Rev.01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Silicone respiratory tubes	G1 015692 0502 Rev.01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Sterile scalpels and scalpel blades	G1 015692 0502 Rev.01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Sterile redon bottles	G1 015692 0502 Rev.01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028

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Sterile suction tubes	G1 015692 0502 Rev.01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Sterile suction kits	G1 015692 0502 Rev.01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Sterile wound drainage systems	G1 015692 0502 Rev.01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Sterile arterial embolectomy catheters	G1 015692 0502 Rev.01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Humidifiers	G1 015692 0502 Rev.01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Artificial noses	G1 015692 0502 Rev.01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Sterile catheters and accessories	G1 015692 0502 Rev.01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Sterile trocar and thoracic catheters	G1 015692 0502 Rev.01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Oxygen therapy accessories	G1 015692 0502 Rev.01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Accessories for respiration	G1 015692 0502 Rev.01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Accessories for respiration	G1 015692 0502 Rev.01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Identy loops	G1 015692 0502 Rev.01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028

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Sterile Dermal Biopsy Punch	G1 015692 0502 Rev.01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Faecal Management System	G1 015692 0502 Rev.01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Disposable neutral electrodes	G1 015692 0502 Rev.01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Balloon catheter	G1 015692 0502 Rev.01	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Sterile skin staplers	G2 015692 0503 Rev.00	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Sterile suction catheter	G2 015692 0503 Rev.00	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Medicine cups	G3M 015692 0506 Rev.00	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028
Urine bag D8	G2MS 015692 0505 Rev.00	26/05/2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31/12/2028

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