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WAGNER Klinikbedarf e.K. – Ronsdorfer Straße 188-190 – 42855 Remscheid

Manufacturer's Declaration

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

- the validity of certificate issued under 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

Manufacturer name	Wagner Klinikbedarf e.K., Inh. Ingo Wagner
Manufacturer address and contact details	Ronsdorfer Str. 188-190, 42855 Remscheid, Germany Phone: +49 (0) 2191 9516311 Fax: +49 (0) 2191 9516329 E-Mail: info@wagner-klinikbedarf.de http://www.wagner-klinikbedarf.de/
Single Registration Number (SRN)	DE-PR-000005010

Notified body name	TÜV NORD CERT GmbH Am TÜV 1 45307 Essen
Notified body number	0044
Directive Certificate number to which this confirmation is made	44 235 200155
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	24.03.2024
End date of extended validity/transition period	31.12.2028
Devices	Sterile procedure packs

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We, as the manufacturer declare under our sole responsibility:

- for the above listed Directive Certificate the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and
- the above listed devices 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,

namely by fulfilling the following conditions:

- **Directive Certificate as listed above**
  - Directive Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.
  - Directive Certificate expired after 20 March 2023.
  - Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made for the devices listed above.
  - A signed written agreement between Wagner Klinikbedarf e.K. and our Notified Body 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.
  - We applied for a confirmation issued by our Notified Body within framework of Regulation (EU) 2023/607.
- **Devices as listed on the first page**
  - The devices continue to comply with the MDD.
  - There are no significant changes in the design and intended purpose.
  - The devices do not represent an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Geschäftsführer/
Verantwortliche Person nach Art. 15 MDR: 16.05.24
(Datum/Unterschrift)

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