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Office: BEROMED GMBH HOSPITAL PRODUCTS · Kronenstrasse 19 · 10117 Berlin · Germany

## Declaration of conformity

**Manufacturer:** Beromed GmbH Hospital Products  
Kronenstrasse 19  
10117 Berlin  
GERMANY

**Name of the product:** Catheter tip syringes (Syringes catheter / Irrigation syringes)

We herewith declare in our own responsibility that the above-mentioned product(s) meet(s) the provisions of the Council Directive 93/42/EEC of 14th June 1993 concerning medical devices, as amended by Council Directive 2007/47/EC.  
All supporting documentation is retained under the premises of the manufacturer (QC department).

**Referenced standard(s) or normative documents:** indicated in the related "List of provisions and standards applied" held by the manufacturer as part of the technical documentation

**Conformity assessment route:** according to Annex VII in conjunction with Annex V of the Council Directive mentioned above

**Classification:** according to annex IX of the Council Directive mentioned above  
Class Is+m

**Notified Body:** TÜV SÜD Product Service GmbH  
(Name, address, identification no) Ridlerstraße 65  
80339 München, Germany  
Identification no: 0123

**EC certificate(s):** G2MS 044082 0042 Rev. 00

**Confirmed transition timeline (MDR Article 120 (3)):** 31.12.2028 (Confirmation Letter CL 044082 0052 Rev. 00)

**Place, date of issue of this declaration:** Berlin, 21.05.2024

**Name, title and signature of authorized person:** Dr. A. Pachten  
(Quality Management Representative, Deputy PRRC)



This Declaration is valid until 31.12.2028 or its next revision.

Currency	<b>USD and EUR</b>	<b>USD</b>	<b>EUR and PLN</b>	Registered Office: Berlin
Bank	Deutsche Bank AG	Commerzbank AG	Commerzbank AG	Managing Director: Jörg Bartz
Bank Code	100 700 00	100 800 00	100 800 00	Commercial Registry: Berlin-
Account No.	605 37 55 00	0905 83 45 01	0905 83 45 00	Charlottenburg HRB 65718
IBAN	DE05 1007 0000 0605 3755 00	DE48 1008 0000 0905 8345 01	DE75 1008 0000 0905 8345 00	VAT-No. DE 812 404 118
SWIFT	DEUT DE BB	DRES DE FF 100	DRES DE FF 100	



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## Attachment to Declaration of conformity G2MS-03-8, revision 2, dated 21.05.2024

### Catheter tip syringes (Syringes catheter / Irrigation syringes)

Article no	Risk Class	UMDNS
B943833	Im+s	13-936
B943833E	Im+s	13-936
B943840	Im+s	13-936
B943840D	Im+s	13-936
B943840E	Im+s	13-936
B943840T	Im+s	13-936
B947107	Im+s	13-936
B947114	Im+s	13-936
B947671	Im+s	13-936
B948371D	Im+s	13-936
B948371E	Im+s	13-936



Currency **USD and EUR**  
Bank Deutsche Bank AG  
Bank Code 100 700 00  
Account No. 605 37 55 00  
IBAN DE05 1007 0000 0605 3755 00  
SWIFT DEUT DE BB

**USD**  
Commerzbank AG  
100 800 00  
0905 83 45 01  
DE48 1008 0000 0905 8345 01  
DRES DE FF 100

**EUR and PLN**  
Commerzbank AG  
100 800 00  
0905 83 45 00  
DE75 1008 0000 0905 8345 00  
DRES DE FF 100

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