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

Summary essential technical data - **BEROBLADE** - Sterile surgical blades for single use

<u>Manufacturer:</u>	Beromed GmbH Hospital Products Kronenstrasse 19 10117 Berlin GERMANY
<u>Product:</u>	Surgical Blades (Sterile surgical blades for single use)
<u>Brand:</u>	BEROBLADE
<u>UMDNS code:</u>	12-252
<u>Risk Class:</u>	IIa according to Annex IX, rule 6 of Council Directive 93/42/EEC, as amended by Council Directive 2007/47/EC
<u>Conformity assessment procedure:</u>	according to Annex II (excl. Section 4) of Council Directive 93/42/EEC, as amended by Council Directive 2007/47/EC
<u>Notified Body:</u>	TÜV Süd Product Service GmbH Ridlerstraße 65 80339 Munich, Germany Identification no 0123

Brief description of the product

Intended use:

BEROBLADE surgical blades are intended for cutting soft tissue in the frame of surgical procedures. They are single-use items and are intended for transient use.

Indications:

Surgical procedures in which soft tissue has to be cut.

Contraindications:

There are no particular medical contraindications for the use of surgical blades. Attention has to be paid and precautions to be taken in patients with blood clotting disorders as capillary vessels are damaged during the cutting process which might lead to excessive bleeding.

BEROBLADE surgical blades enable the surgeon to precisely cut the human tissue and allow for the surgical wounds to heal without complications.

BEROBLADE surgical blades are suitable for all standard handles (fitments 3 resp. 4).

Standards applied: indicated in the list of provisions and standards applied, identifier BPO112IIa-3

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Bank Code	100 700 00	100 800 00	Managing Director: Jörg Bartz
Account No.	605 37 55 00	905 83 45 00	Commercial Registry: Berlin-Charlottenburg HRB 65718
IBAN	DE05 1007 0000 0605 3755 00	DE75 1008 0000 0905 8345 00	VAT-No. DE 812 404 118
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Material specifications:

A. Stainless steel, 6Cr13

Composition of alloy	
Chemical element	%
C	0,591
Cr	13,20
Si	0,478
P	0,025
S	0,001
Mn	0,439

rigidity ≥ 650HV10

B. Carbon steel, T10A

Composition of alloy	
Chemical element	%
C	0,96
Mn	0,21
S	0,009
P	0,008
Si	0,24
Ni	0,03
Cr	0,05
Cu	0,11

rigidity ≥ 750HV10

Physical features

blades in big sizes:

Width of the small side of the hole	1.95 - 2.0 mm
Width of the large side of the hole	3.72 - 3.77 mm
length of the hole	24.2 - 24.27 mm
dimension of the ending angle	7.5 - 7.65 °

blades in small sizes:

Width of the small side of the hole	1.18 - 1.23 mm
Width of the large side of the hole	2.43 - 2.48 mm
length of the hole	17.83 - 17.9 mm
dimension of the ending angle	4.5 - 4.65 °

Cutting capacity ≤ 0.8 N

Warp amount ≤ 0.1 mm

Roughness Ra ≤ 0.4 µm

Sterilization: by gamma irradiation

Latex: *BEROBLADE* is latex-free

Shelflife: 5 years from the date of manufacture
date of expiry is indicated on the individual package

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Packing data:

	Quantity (pieces)	dimensions
individual package	1	alufoil, antirust paper, 87 x 25 mm
inner box	100	0.091 x 0.068 x 0.03 m
export carton	5000	0.36 x 0.325 x 0.110 m

Storage: Store in a clean environment - relative humidity not higher than 80 %

Precautions for use: The operators should be professionally trained medical staff.

Check the integrity of the individual package before use. Do not use if the package is damaged.

To be used immediately when individual package is opened.

Do not re-sterilize.

For single use only. Re-use of single-use devices creates a potential risk of patient or user. It may lead to contamination and/or impairment of functional capability. Contamination and/or limited functionality of the device may lead to injury, illness or death of the patient.

Discard after single use in a sharps container to avoid risk of injuries and infection.

Use within the validity period.

Variants:

BERO BLADE, Sterile surgical blade for single use, carbon Steel

Article no	Fitment no	Size/Figure	Risk Class
B420105	3	10	Ila
B420112	3	11	Ila
B420129	3	12	Ila
B420136	3	13	Ila
B420150	3	15	Ila
B420181	4	18	Ila
B420198	4	19	Ila
B420204	4	20	Ila
B420211	4	21	Ila
B420228	4	22	Ila
B420235	4	23	Ila
B420242	4	24	Ila
B420259	4	25	Ila
B420365	4	36	Ila

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BEROBLADE, Sterile surgical blades for single use, stainless steel

Article no	Fitment no	Size/Figure	Risk Class
B430104	3	10	Ila
B430111	3	11	Ila
B430128	3	12	Ila
B431811	3	13	Ila
B430159	3	15	Ila
B430166	3	16	Ila
B430180	4	18	Ila
B430197	4	19	Ila
B430203	4	20	Ila
B430210	4	21	Ila
B430227	4	22	Ila
B430234	4	23	Ila
B430241	4	24	Ila
B431828	4	36	Ila

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