

Declaration of Conformity

Manufacturer	GELITA MEDICAL GmbH Uferstrasse 7 69412 Eberbach Germany
Product	Hemostatic, Surgical, brandname: GELITA-CEL® STANDARD Absorbable Oxidized Cellulose Gauze Hemostat Hemostatic, Surgical, brandname: GELITA-CEL® X-SORB Absorbable Oxidized Cellulose Gauze Heavy Duty Hemostat Hemostatic, Surgical, brandname: GELITA-CEL® FIBRILLAR Absorbable Oxidized Cellulose Non-Woven Hemostat
UMDNS Code	17944
GMDN Code	38771
Product Code(s)	See addendum product list for details
Applicable Directives and Standards	Council Directive 93/42/EEC of June 14th, 1993 concerning medical devices All other relevant Harmonized Standards as published in the Official Journal of the European Communities are applicable to this type of product.
Classification	MDD Annex IX, Class III, Rule 8
Conformity Assessment	MDD Annex II, section 3 and 4
Notified Body details	DEKRA, Certification B.V. Meander 1051 6825 MJ ARNHEM The Netherlands Notified Body Number: 0344
Certificates	CE MARKING OF CONFORMITY MEDICAL DEVICES Number: 2141242CE02 Validity: 1 st December 2023 EC DESIGN EXAMINATION MEDICAL DEVICES Number: 2141242DE02 Validity: 30 th November 2022
Date CE mark first affixed GELITA-CEL® STANDARD	22th of August 2011
Date CE mark first affixed GELITA-CEL® X-SORB, GELITA-CEL® FIBRILLAR	13th of August 2012
Current Validity	1 st December 2023

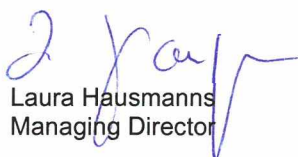
We, GELITA MEDICAL GmbH, herewith declare that all above mentioned products meet the provisions of the MEDICAL DEVICE DIRECTIVE 93/42 EEC and applicable standards. All supporting documentations are retained under the premises of the manufacturer and the notified body.

Place / Date Eberbach, 14th January, 2019

Signature / Stamp

Name
Position

Laura Hausmanns
Managing Director



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• Volksbank Neckartal eG • IBAN: DE 40 6729 1700 0020 2142 01 • BIC: GENODE61NGD

• Deutsche Bank AG • IBAN: DE 13 6727 0003 0031 4609 00 • BIC: DEUTDE33HAN

• VAT/USt.-IdNr. DE 812 919 302

District Court: Mannheim HRB-Nr. 337927 • Geschäftsführerin / Managing Director: Laura Hausmanns

This product list belongs to the Declaration of Conformity identified by GELITA MEDICAL GmbH and specifies the CE marked products that GELITA MEDICAL GmbH intends to distribute in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

The following list identifies the products by Device Name and sizes.

Device Name		
GELITA-CEL [®] STANDARD		
REF	Quantity	Size
GC-501	(Qty 15)	50 x 12,5 mm
GC-507	(Qty 15)	50 x 70 mm
GC-510	(Qty 15)	70 x 100 mm
GC-535	(Qty 10)	50 x 350 mm
GC-540	(Qty 10)	100 x 200 mm

Device Name		
GELITA-CEL [®] X-SORB		
REF	Quantity	Size
GX-603	(Qty 15)	25 x 25 mm
GX-608	(Qty 10)	50 x 75 mm
GX-609	(Qty 15)	25 x 90 mm
GX-610	(Qty 10)	70 x 100 mm
GX-620	(Qty 10)	140 x 200 mm

Device Name		
GELITA-CEL [®] FIBRILLAR		
REF	Quantity	Size
GF-705	(Qty 10)	25 x 50mm
GF-708	(Qty 10)	50 x 75 mm
GF-710	(Qty 10)	50 x 100 mm
GF-711	(Qty 10)	100 x 100 mm

Place / Date

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Position

Laura Hausmanns
Managing Director

GELITA[®]
MEDICAL

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DoC GELITA CEL X-SORB + FIBRILLAR + STANDARD

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