GELITA® MEDICAL
Complete Care! Completely Safe!

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 GMDN Code	17944 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 Conformity Assessment	MDD Annex IX, Class III,Rule 8 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: 1st December 2023 EC DESIGN EXAMINATION MEDICAL DEVICES Number: 2141242DE02 Validity: 30th 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	1st 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	GELITA® MEDICAL GELITA MEDICAL GmbH Uferstraße 7 69412 Eberbach Germany Tel.: +49 6271 84-01 Fax: +49 6271 84-2700
Name	Laura Hausmanns
Position	Managing Director

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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 — Eberbach, 14th January, 2019

Signature / Stamp

Name — Laura Hausmanns

Position — Managing Director

GELITA® MEDICAL

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