

B. Braun Medical AG  
Seesatz 17  
6204 Sempach  
Switzerland

## DECLARATION OF CONFORMITY

**Product Category:** Medical devices for Wound Bed Preparation

Product (Name, Type)	Size	Date of CE marking/ Batch No.	Remarks
LavaSurge®	250 ml	01.02.2017/ 16343M26	
	1000 ml	01.02.2017/ 16343M26	

Article numbers: see attachment

<b>Conformity Assessment Procedure</b>	acc. to ANNEX II excluding (4) of the COUNCIL DIRECTIVE 93/42/EEC
<b>Classification</b>	acc. to ANNEX IX of the COUNCIL DIRECTIVE 93/42/EEC
<b>Class / Rule</b>	Class IIb / Rule 4
<b>Applied Standards</b>	EN ISO 13485:2016, Certificate No. Q5 061585 0030
<b>CE Certificate</b>	No. 2113812CE01, valid until May 26, 2024
<b>Notified Body</b>	DEKRA Certification B.V., Meander 1051, 6825 MJ Arnhem, The Netherlands
<b>Identification no.</b>	0344
<b>EC REP</b>	B. Braun Melsungen AG, Carl-Braun-Strasse 1, 34212 Melsungen, Germany

We herewith declare under our sole responsibility that the above mentioned product meets all the provisions of the COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices as amended by Directive 2007/47/EC, which apply to them, as stated in ANNEX II.

Sempach, 13.04.2021

B. Braun Medical AG

  
Peter Egli  
Head of Quality Management  
CoE Infection Prevention & Renal Fluids

  
Dr. Michael Gluschke  
Director Global Regulatory Affairs  
CoE Infection Prevention & Renal Fluids

**DECLARATION OF CONFORMITY**  
**Attachment for Medical Devices Class IIb**

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<b>Art. No.</b>	<b>Product Name</b>	<b>Remarks</b>
19901	LavaSurge® (250 ml)	
19902	LavaSurge® (1000 ml)	