EC DESIGN-EXAMINATION CERTIFICATE

Number: 2113812DE06

Directive 93/42/EEC on Medical devices, Annex II (4)
(Devices in Class III)

Manufacturer:

B. Braun Medical AG

Seesatz 17
6204 Sempach
Switzerland

For the product

Prontosan Wound Spray

Documents, that form the basis of this certificate:

Certification Notice 2113812CN, initially dated 12 February 2008
Addendum, initially dated 26 February 2016

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 March 2023
Issued for the first time: 1 March 2016
Reissued: 12 April 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 2113812DE06

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Prontosan Wound Spray

Issued to:

B. Braun Medical AG
Seesatz 17
6204 Sempach
Switzerland

This certificate covers the following product(s):

Prontosan Wound Spray 75 ml
Viscoplast

Initial date: 26 February 2016
Revision date: 12 April 2018

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