EC DESIGN-EXAMINATION CERTIFICATE

Number: 2113812DE02

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

Manufacturer:
B. Braun Medical AG
Seesatz 17
6204 Sempach
Switzerland

Digitally signed by Moraru Grigore
Date: 2023.09.29 10:20:49 EEST
Reason: MoldSign Signature
Location: Moldova

For the product

Prontosan Wound Irrigation Solution

Documents, that form the basis of this certificate:

Certification Notice 2113812CN, initially dated 12 February 2018
Addendum, initially dated 1 March 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: 26 May 2024
Issued for the first time: 1 March 2016
Reissued: 3 December 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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

ADDENDUM

Belonging to certificate: 2113812DE02

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Prontosan Wound Irrigation Solution

Issued to:

B. Braun Medical AG
Seesatz 17
6204 Sempach
Switzerland

This certificate covers the following product(s):

Prontosan Wound Irrigation Solution:
- 6 x 40 ml ampoule
- 10 x 350 ml
- 350 ml
- 10 x 1000 ml
- 24 x 40 ml
- 1000 ml

Initial date: 1 March 2016

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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

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