

EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC,
Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company
BSN medical GmbH

Quickbornstraße 24, 20253 Hamburg, Germany
POB: 22771, Hamburg, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50708-Z6-00, the decision dated 2019-06-17 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-06-17 to 2024-05-26

Registration No.: 50708-16-09

A handwritten signature in black ink, appearing to read 'Ruth Delbeck-Bayer', written over a horizontal line.



Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-06-17
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Annex to the EC Certificate No. 50708-16-09

Valid from 2019-06-17 to 2024-05-26

Revision status of the annex: 0 dated 2019-06-17

Devices/device categories included in the certificate:

Class I s:

For the products listed below, review of the Quality Assurance System refers exclusively to aspects of manufacture concerned with securing and maintaining sterile conditions.

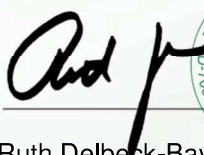
- Adhesive bandage
- Adhesive strips for wound closure
- Bandage with woundpad
- Compresses
- Skin stapler remover
- Sterile skin barrier film
- Urinary drainage system
- NPWT Vacuum pad

Class II a:

- Blister Plaster
- Cold pack
- Cold Spray
- Compresses
- Foley Catheters
- Skin Adhesives
- Skin Stapler
- Urinary catheterization kits
- NPWT Abdominal Organ Protection Layer (OPL)
- Negative-Pressure Wound Therapy System Pump

Class II b:

- Dressings for wound healing by secondary intention
- Foley Catheters
- Debridement pad



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