

# 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, Deutschland  
Post-Office Box address: 570239, 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 2020-12-15 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2020-12-15 to 2024-05-26

Registration No.: 50708-16-10

*Ruth Delbeck-Bayer*

Ruth Delbeck-Bayer  
DEKRA Certification GmbH Stuttgart; 2020-12-15  
Notified Body ID-number: 0124

DEKRA Certification GmbH \* Handwerkstraße 15 \* D-70565 Stuttgart \* [www.dekra.de/audits](http://www.dekra.de/audits)



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
**ZLG-BS-295.10.02**

# Annex to the EC Certificate No. 50708-16-10

Valid from 2020-12-15 to 2024-05-26

Revision status of the annex: 0 dated 2020-12-15

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



Ruth Delbeck-Bayer  
DEKRA Certification GmbH, Stuttgart, 2020-12-15  
Notified Body ID-number: 0124

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