EU Certificate

for the assessment of the quality management system

according to Medical Device Regulation (EU) 2017/745 Annex IX Chapter I+III

As a Notified Body of the European Union DEKRA Certification GmbH certifies, that the manufacturer

BSN medical GmbH

Single Registration Number (SRN): DE-MF-000005787
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applies a quality management system according to Annex IX Chapter I+III of the Medical Device Regulation (EU) 2017/745 for the medical devices listed in the annex. This certificate is based on the assessments listed in CNo50708-00 and is only valid in conjunction with the successful completion of the annual surveillance audits.

EU Certificate no.: 50708-60-05-05

Certificate valid from: 2025-02-10
Certificate valid to: 2025-12-14

Previous certificate no. 50708-60-05-04, issued on 2024-09-26

Digitally signed by Markus Lehmann
Date: 2025-02-10 14:52:31+01:00

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-092

DEKRA Certification GmbH, Stuttgart 2025-02-10
Notified Body ID number: 0124

Annex to the EU Certificate no. 50708-60-05-05

Following devices/device categories are included in this certificate:

Class Is

For the devices listed below, the review of the quality management system refers exclusively to the aspects relating to establishing, securing and maintaining sterile conditions.

Barrier dressing

- Cutimed PROTECT, Basic-UDI-DI: 404280940039625A4

Surgical Site Dressings

- Leukomed, Leukoplast leukomed, Basic-UDI-DI: 4042809400415718R
- Leukomed skin sensitive, Basic-UDI-DI: 40428094004730092
- Leukomed T, Basic-UDI-DI: 4042809400415558T
- Leukomed T plus, Leukoplast leukomed T plus, Basic-UDI-DI: 4042809400415899C
- Leukomed I.V. film, Basic-UDI-DI: 4042809400416508N
- Leukomed I.V. non-woven, Basic-UDI-DI: 4042809400416208D
- Leukomed T skin sensitive, Basic-UDI-DI: 404280940046856AF
- Leukomed T plus skin sensitive, Basic-UDI-DI: 404280940046857AH

Medical Tapes

- Leukoplast strong, Basic-UDI-DI: 40428094003421 98J
- Leukoplast barrier, Basic-UDI-DI: 4042809400341598R, Basic-UDI-DI: 4042809400341718F
- Leukoplast visual, Basic-UDI-DI: 4042809400341838N
- Leukoplast detectable, Basic-UDI-DI: 4042809400341958V,
  Basic-UDI-DI: 40428094003420 78B
- Leukoplast universal, Basic-UDI-DI: 4042809400343278N
- Leukoplast strong, Basic-UDI-DI: 40428094003707 28Z

Wound closure strips

- Leukoplast wound closure strip, Basic-UDI-DI: 404280940045987AQ
- Leukoplast Leukosan Strip, Basic-UDI-DI: 404280940049536AF

Compresses

- Leukoplast compress absorbent protect, Basic-UDI-DI: 404280940049853AW
- Leukoplast compress non-woven, Basic-UDI-DI: 404280940049858B8
- Leukoplast compress cotton gauze, Basic-UDI-DI: 404280940048596AS
- Leukoplast compress absorbent soft, Basis-UDI-DI: 404280940049821AH
- Leukoplast Cutisoft soft compress, Basic-UDI-DI: 404280940049863AZ
- Leukoplast swab ball gauze, Basic-UDI-DI: 404280940048588AT
- Leukoplast cotton wool, Basic-UDI-DI: 404280940049856B4

Class IIa

Compresses

- Leukoplast swab abdominal, Basic-UDI-DI: 404280940048586AP
- Leukoplast swab abdominal, Basis UDI-DI: 404280940048587AR
- Leukoplast swab ball gauze, Basis UDI-DI: 404280940048589AV

Annex to the EU Certificate no. 50708-60-05-05

Leukoplast compress cotton gauze, Basis UDI-DI: 404280940048594AN,

Basis UDI-DI: 404280940048597AU

- Leukoplast swab preparation, Basis UDI-DI: 404280940049859BA
- Leukoplast compress viskers, Basis UDI-DI: 404280940049861AV

Thermotherapy

- Tensocold, Basic-UDI-DI: 40428094004534294

Class IIb

Hydroactive wound dressings

- Cutimed Siltec B, Leukoplast Cutimed Siltec B, Cutimed Siltec Sacrum, Basic-UDI-DI: 4042809400407908Y

Intended use:

Cutimed Siltec B, Leukoplast Cutimed Siltec B and Cutimed Siltec Sacrum are intended for the treatment of exuding wounds with low to high exudate levels and for the prevention of pressure ulcers

- Cutimed Sorbion Sachet, Basic-UDI-DI: 4042809400490229B

Intended use:

Cutimed Sorbion Sachet is intended for the treatment of wounds with moderate to excessive exudate levels

- Cutimed Siltec, Leukoplast Cutimed Siltec, Basic-UDI-DI: 40428094004348399

Intended use:

Cutimed Siltec, Leukoplast Cutimed Siltec, is indicated for the treatment of low to high exuding wounds and for the prevention of pressure ulcers

- Cutimed Siltec L, Basic-UDI-DI: 4042809400434859D

Intended use:

Cutimed Siltec L is indicated for the treatment of low to moderate exuding wounds and for the prevention of pressure ulcers

- Cutimed Siltec PLUS, Basic-UDI-DI: 4042809400434869F

Intended use:

Cutimed Siltec PLUS is indicated for the treatment of low to high exuding wounds and for the prevention of pressure ulcers

- Cutimed Cavity, Basis-UDI-DI: 4042809400434889K

Intended use:

Cutimed Cavity is indicated for the management of chronic and acute deep wounds with moderate to high exudate levels

- Cutimed Gelling Fiber, Basic-UDI-DI: 4042809400368109C

Intended use:

Cutimed Gelling Fiber is intended for the treatment of dry to highly exuding wounds and to absorb exudate

- Cutimed Siltec Heel (3D), Basic-UDI-DI: 4042809400434849B

Intended use:

Cutimed Siltec Heel (3D) foam dressings are indicated for the treatment of exuding wounds with low to high exudate levels and for the prevention of pressure ulcers

Annex to the EU Certificate no. 50708-60-05-05

Cutimed Siltec PLUS Heel, Basic-UDI-DI: 4042809400434879H

Intended use:

Cutimed Siltec PLUS Heel foam dressings are indicated for the treatment of exuding wounds with low to high exudate levels and for the prevention of pressure ulcers

- Cutimed Sorbion Border, Basic-UDI-DI: 4042809400368059K

Intended use:

Cutimed Sorbion Border is intended for the treatment of exuding wounds with moderate to excessive levels healing by secondary intention

- Cutimed Sorbion Sana, Basis UDI-DI: 4042809400490399U

Intended use:

Cutimed Sorbion Sana is intended for the treatment of wounds with low to excessive exudate levels

- Cutimed Sorbion Sana Gentle, Basis UDI-DI: 4042809400490499X

Intended use:

Cutimed Sorbion Sana Gentle is intended for the treatment of wounds with low to excessive exudate levels

- Cutimed Sorbion Carbon+ Basic UDI-DI: 4042809400367 99AH

Intended use:

Cutimed Sorbion Carbon+ is intended for the treatment of wounds with moderate to excessive exudate levels

- Leukomed Control, Basic UDI-DI: 4042809400512298N

Intended use:

Leukomed Control is indicated for dry and low exuding acute wounds

- Cutimed Gel, Basic UDI-DI: 4042809400490 78A6

Intended use:

Cutimed Gel produces a moist, physiological wound environment and supports autolytic cleansing of necrotic or unclean wounds

<u>Wound Debridement</u>

- Cutimed DebriClean, Basis-UDI-DI: 4042809400407999J

Intended use:

Cutimed DebriClean aids in the debridement of superficial wounds and surrounding skin

<u>Wound contact layer</u>

- Cutimed Sorbion Plus, Basic UDI-DI: 4042809400440918T

Intended use:

Cutimed Sorbion Plus is intended to be used as an atraumatic wound contact layer for the treatment of exuding wounds

- Cutimed Cuticell, Basic UDI-DI: 4042809400462699S

Intended use:

Cutimed Cuticell is a primary wound contact layer indicated for the treatment of superficial exudating wounds

- Cutimed Cuticell, Classic, Basic UDI-DI: 4042809400490669X

Intended use:

Cutimed Cuticell Classic is a primary wound contact layer indicated for the treatment of superficial exuding wounds

Annex to the EU Certificate no. 50708-60-05-05

- Leukoplast Cuticell Classic, Basic UDI-DI: 40428094005012582

Intended use:

Leukoplast Cuticell Classic is a primary wound contact layer indicated for the treatment of superficial exuding wounds

Change(s) to previous certificate: Certificate extension to include new variants in existing product groups (Change Notification no. 50708-CN24-13).