

We,

**BSN medical GmbH
Schützenstr. 1-3
22761 Hamburg
Germany
(SRN: DE-MF-000005787)**

hereby declare under our sole responsibility, that this product family complies with the applicable requirements of the regulation (EU) 2017/745 of the European parliament and of the council on medical devices (MDR).

Product Name:

Leukoplast® detectable

Basic UDI-DI:

4042809400342078B

Intended purpose:

Leukoplast® detectable (sterile) is intended for minor wounds like cuts, lacerations, abrasions or as cover of puncture sites after blood withdrawal or vaccination. Especially for situations where dressing needs to be visible if lost.

Conformity assessment route: **Annex IX, Chapter I**

Classification rule:

4

Classification:

Is

The Declaration of Conformity is performed in accordance with the quality management system according to EN ISO 13485, and fulfils the general safety and performance requirements of the regulation (EU) 2017/745.

This declaration is only valid in conjunction with the current E.C. certificates issued by DEKRA Certification GmbH (Id. No. 0124), Handwerkstraße 15, 70565 Stuttgart, Germany.

Number of E.C. certificate: 50708-60-04

Declaration of conformity issued: 06.05.2024

Compiled and released:

Hamburg, 06.05.2024
Dr. Thomas Mehler
Global Quality Director Medical
BSN medical GmbH



Digitally signed by
Thomas.Mehler
DN: cn=Thomas.Mehler
Date: 2024.05.06 09:53:41
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Article	Description	REF
76453-00001-02	LEUKOPLAST DETECTABLE STERILE 28X72MM BLUE 50 DA NL EN FI FR DE IT NO PT ES SV	76453-01
76453-00003-02	LEUKOPLAST DETECTABLE STERILE 22X72MM BLUE 100 DA NL EN FI FR DE IT NO PT ES SV	76453-03
76453-00004-02	LEUKOPLAST DETECTABLE STERILE 50X72MM BLUE 100 DA NL EN FI FR DE IT NO PT ES SV PATCH	76453-04
76453-00006-02	LEUKOPLAST DETECTABLE STERILE 38X38MM(20) 50X72MM(15) 22X72MM(40) 44X50MM(10) 19X120MM(10) BLUE 1 DE DA EN FI FR IT NL NO SV ES (95D)	76453-06