

EU DECLARATION OF CONFORMITY

DOC-0027-04

We declare under our sole responsibility that the following products comply with Regulation (EU) 2017/745 (MDR) on medical devices.

Manufacturer	Lohmann & Rauscher International GmbH & Co. KG Westerwaldstraße 4 56579 Rengsdorf Germany
SRN	DE-MF-000005052
Product Group	Cohesive Conforming Bandages
Catalogue numbers & product names	See document DI_REF_00017_02
Intended Purpose	For retention and for immobilization
Basic UDI-DI	4021447-0027-KH (sterile); 4021447-0027NST-6M (non-sterile)
Class / Rule	I/01 + Is/01

Conformity Assessment Route	Class 1 non sterile variants: Technical documentation according to annexes II and III of Regulation (EU) 2017/745 Class 1 sterile variants: Annex XI Part A of Regulation (EU) 2017/745
------------------------------------	--

Notified Body:	Only applicable for Basic UDI-DI 4021447-0027-KH
	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Germany Identification number: 0123 <u>Certificate identification:</u> G21 045286 0081 <u>Device Group on Certificate:</u> M03 BANDAGES

Neuwied

Place

Lohmann & Rauscher International GmbH & Co. KG
Oliver Opitz, PRRC-Q