CE Declaration of Conformity

In accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council of 05 April 2017 concerning medical devices

Medical Device	**Family: Bandages, non-sterile**

Roll Plaster
ABE® silk (REF 9531, 9535, 9536, 9540, 9541)
BeeSana® SafeCut (REF 1844)

Fixation Bandages
ABE® Last (REF 1409, 1410, 1411, 1412, 1413)
ABE® universal (REF 1414, 1415, 1416, 1432, 1433, 1434)
ABE® Last krepp (REF 1749, 1750, 1751, 1752, 1753)
ABE® lastic (REF 1780, 1781, 1782, 1783, 1784, 1785, 1786)
ABE® extra (REF 1421, 1422, 1735, 1736, 1737, 1737, 1738)
ABE® Last haft (REF 1288, 1289, 1391, 1392, 1393, 1394, 1383, 1384, 1385, 1386)
ABE® fix haft c (REF MEP 1396, MEP 1397, MEP 1398)

Gauze Bandages
ABE® Mullbinde (REF 1400, 1401, 1402, 1403, 1404)

Tubular Bandages
ABE® Trikotschlauchverband (REF: 5181, 5182, 5183, 5184, 5185, 5186, 5187, 5189)
ABE® Netzschlauchverband (REF: 5164, 5166, 5170, 5172, 5176, 5180)

Non-Woven Fixation
ABE® Fixiervlies (REF: 4470, 4471, 4472, 4473)

Paddig Bandages
ABE® Polsterbinde (REF: 1701, 1702, 1703, 1806)

Intended use	The medical devices are used for the fixation of wound dressings or the fixation of other products such as hollow needles, drainages or tubings. They are used as mechanical barriers, for light compression or for fixation of primary wound dressings and as padding material.

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Basis UDI-DI according to Annex VI, Part C	GMN42500164W004bandagesns6X
Medical device class according to Annex VIII	I
Chosen conformity assessment procedure	The technical documentation according to Annex II and Annex III of Regulation (EU) 2017/745 is available.
CE-mark since	Since 1998 according to 93/42/EEC and since 05.2021 according to Regulation (EU) 2017/745.
Validity of this CE Declaration of Conformity	08.12.2025

Manufacturer	Meditrade GmbH Medipark 1 83088 Kiefersfelden
Single Registration Number according to Article 31	DE-MF-000008937

We hereby declare in our sole responsibility the conformity of the above medical device with Regulation (EU) 2017/745 of the European Parliament and of the Council of 05 April 2017 on medical devices.

Meditrade hereby declares that medical devices covered by this declaration comply with this Regulation and, where applicable, with other relevant Union provisions which require the issuance of an EU declaration of conformity.

Common specifications applied:

There are no common specifications for these devices according to Article 9 of Regulation (EU) 2017/745.

Kiefersfelden, 09.12.2022

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Martin Unterberg, PRRC

Person responsible for regulatory compliance under Article 15 of Regulation (EU) 2017/745, Meditrade GmbH