Certificate No: BAX DOC-140421

EC Declaration of Conformity

Manufacture:	**biviax GmbH & Co KG, Hagener Str. 428, 44229 Dortmund, Germany**
SRN (Single Registration Number)**:**	**DE-MF-000005476**
Basic UDI-DI:	**426016822 0026M**
Name of Devices:	**Crosstape**
HS code:	**3005001000**
Classification:	**Class I (Council Directive (EU) 2017/745 (MDR)** **Rule: According to Rule 1, Annex VIII, Chapter III of EU Medical Device Regulation (EU 2017/745)**
Conformity assessment route:	**biviax GmbH & Co KG uses the following procedures for the CE-labeling of their products according to the regulation MDR 2017/745, Annex II+III.**
Standards applied:	**EN ISO 14971/2020, EN ISO 10993-1:2021, ISO 15223 – 1:2022, IEC62321:2017, EN1041.2013, MEDDEV 2.7.1/Rev. 4, ISO 9001/2015**

This declaration of conformity is issued under the sole responsibility of biviax GmbH & Co KG. We hereby declare that the medical devices specified above meet the provision of the regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to DIN (EU) ISO 9001/2015 issued by TÜV Süd Germany.

All supporting documentation is retained at the premises of the manufacturer.

This declaration of conformity applies to all K-Tape products that are listed in Annex I with the respective article number and EAN Code.

CE

Date: April 10, 2025

Signature:

Ingo Kumbrink / President

Date of Expiry 31.05.2028

Annex I

EAN Code		Item number Supplier	Commercial Description
Crosstape			
4260168221006		200100	Crosstape S-Size, 20 Sheets, 400 Tapes
4260168221013		200101	Crosstape M-Size, 20 Sheets, 180 Tapes
4260168221020		200102	Crosstape L-Size, 20 Sheets, 120 Tapes
4260168221037		200103	Crosstape XL-Size, 20 Sheets, 40 Tapes
4260168222249		200224	Crosstape Mix, 6 Sheets, 55 Tapes (20xS, 27xM, 6xL, 2xXL)