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-M F000005476**
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 the Regulation MDR 2017/745, Annex II+III:**
Standards applied:	**EN ISO 14971/2020, EN ISO 10993-1:2010, ISO 15223 – 1:2013, 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 Crosstape products that are listed in Appendix I with the respective article number and EAN Code.

CE

Date: May 24,2021

Signature:

biviax GmbH & Co. KG
Hagener Straße 428 · D-44229 Dortmund
Fon +49 231. 97 67 301 · Fax +49 231. 97 67 302

68bi/Kum/05/2021

Date of Expiry 31.12.2023

Certificate No: BAX DOC-140421

Ingo Kumbrink / President

Annex I

Crosstape		
EAN	**Item number supplier**	
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)