Certificate No: BAX DOC-130426

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 0016K**
Name of Devices:	**K-Tape**
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
			K-Tape Original
4260168221112		100111	K-Tape Red Single Roll 5mx5cm
4260168221129		100112	K-Tape Blue Single Roll 5mx5cm
4260168221136		100113	K-Tape Beige Single Roll 5mx5cm
4260168221143		100114	K-Tape Black Single Roll 5mx5cm
4260168221419		100141	K-Tape Red Box of 4 Rolls, 5m each
4260168221426		100142	K-Tape Blue Box of 4 Rolls, 5m each
4260168221433		100143	K-Tape Beige Box of 4 Rolls, 5m each
4260168221440		100144	K-Tape Black Box of 4 Rolls, 5m each
4260168221457		100145	K-Tape Mixpack Box of 4 Rolls (one per colour), 5m each
4260168221617		100161	K-Tape Red XXL Single Roll 22mx5cm
4260168221624		100162	K-Tape Blue XXL Single Roll 22mx5cm
4260168221631		100163	K-Tape Beige XXL Single Roll 22mx5cm
4260168221648		100164	K-Tape Black XXL Single Roll 22mx5cm
			K-Tape My Skin
4260168221150		100115	K-Tape My Skin Beige Single Roll 5mx5cm
4260168221167		100116	K-Tape My Skin Light Brown Single Roll 5mx5cm
4260168221174		100117	K-Tape My Skin Medium Brown Single Roll 5mx5cm
4260168221181		100118	K-Tape My Skin Dark Brown Single Roll 5mx5cm
4260168221198		100119	K-Tape My Skin Very Dark Brown Single Roll 5mx5cm
4260168221464		100146	K-Tape My Skin Beige Box of 4 Rolls, 5m each
4260168221471		100147	K-Tape My Skin Light Brown Box of 4 Rolls, 5m each
4260168221488		100148	K-Tape My Skin Medium Brown Box of 4 Rolls, 5m each
4260168221495		100149	K-Tape My Skin Dark Brown Box of 4 Rolls, 5m each
4260168221501		100150	K-Tape My Skin Very Dark Brown Box of 4 Rolls, 5m each
4260168221518		100151	K-Tape My Skin Mixed Box of 5 Rolls (once per colour), 5m each
4260168221761		100176	K-Tape My Skin Beige XXL Single Roll 22mx5cm
4260168221778		100177	K-Tape My Skin Light Brown XXL Single Roll 22mx5cm
4260168221785		100178	K-Tape My Skin Medium Brown XXL Single Roll 22mx5cm
4260168221792		100179	K-Tape My Skin Dark Brown XXL Single Roll 22mx5cm

4260168221808		100180	K-Tape My Skin Very Dark Brown Single Roll XXL 22mx5cm
K-Tape Pure			
4260168221204		100120	K-Tape Pure Single Roll 5mx5cm
4260168221525		100152	K-Tape Pure Box of 4 Rolls, 5m each
4260168221815		100181	K-Tape Pure XXL Single Roll 22mx5cm

K-Tape Lymph			
4260168225257		100525	K-Tape Lymph Pre-Cut 25cm 20 tapes, 5m total
4260168225400		100540	K-Tape Lymph Pre-Cut 40cm 12 tapes, 4,8m total
K-Tape for me			
4260168221051		100105	K-Tape for me for shoulder and neck tensions 2 Pre-Cuts
4260168221068		100106	K-Tape for me for the relief of wrist or knee pain 2 Pre-Cuts
4260168221075		100107	K-Tape for me for back pain 4 Pre-Cuts
4260168221082		100108	K-Tape for me for menstrual pain or bladder disorders 3 Pre-Cuts (2x150mm, 1x100mm)
4260168221099		100109	K-Tape for me for hematomas 4 Pre-Cuts
4260168221105		100110	K-Tape for me for ankle pain 2 Pre-Cuts (1x150mm, 1x300mm)
K-Tape Cut			
4260168226117		100611	K-Tape Cut15 red
4260168226124		100612	K-Tape Cut 15 blue
4260168226131		100613	K-TapeCut15 beige
4260168226148		100614	K-Tape Cut15 black
4260168226216		100621	K-Tape Cut20 red
4260168226223		100622	K-Tape Cut20 blue
4260168226230		100623	K-Tape Cut 20 beige
4260168226247		100624	K-Tape Cut20 black
4260168226315		100631	K-Tape Cut30 red
4260168226322		100632	K-Tape Cut30 blue
4260168226339		100633	K-Tape Cut30 beige
4260168226346		100634	K-Tape Cut30 black
K-Tape Team			
4260168228012		100801	Team Sport Blue & Sport Red
4260168228029		100802	Team Black & White
4260168228036		100803	Team Green & White

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4260168228043		100804	Team Sport Red & White
4260168228050		100805	Team Sport Bue & White
4260168228067		100806	Team Black & Sport Red
4260168228074		100807	Team Sport Blue & Orange
4260168228081		100808	Team Orange & White
4260168228098		100809	Team Black & Yellow
4260168228104		100810	Team Yellow & Green
4260168228111		100811	Team Sport Blue & Blue
4260168228128		100812	Team Yellow & Sport Blue
4260168228135		100813	Team Yellow & Black (box with grey letters)
4260168228142		100814	Team Yellow& Black
4260168228159		100815	Team Orange & Black
4260168228166		100816	Team Sport Blue & Sport Red
4260168228173		100817	Team Sport Red & Yellow
4260168228180		100818	Team Sport Blue & Yellow
4260168228197		100819	Team Sport Red & Black
4260168228203		100820	Team Orange & Blue
4260168228210		100821	Team Green & Sport Blue
4260168228227		100822	Team Red & Blue
4260168228234		100823	Team White & Blue
4260168228241		100824	Team White & Red
4260168228258		100825	Team Sport Red & Sport Red
4260168228265		100826	Team Orange & Orange
4260168228272		100827	Team Yellow & Yellow
4260168228289		100828	Team White & White
4260168228296		100829	Team Black & Black
4260168228302		100830	Team Sport Blue & Sport Blue
4260168228319		100831	Team Green & Green
4260168228326		100832	Team Blue & Blue
4260168228333		100833	Tea Red & Red
4260168221211		100121	K-Tape Team Yellow
4260168221228		100122	K-Tape Team Sport Red
4260168221235		100123	K-Tape Team Sport Blue
4260168221242		100124	K-Tape Team Green
4260168221259		100125	K-Tape Team Orange