



EC Declaration of Conformity

Manufacture: biviax GmbH & Co KG, Hagener Str. 428, 44229 Dortmund, Germany

SRN: DE-M F000005476
(Single Registration Number)

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 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 K-Tape products that are listed in Appendix I with the respective article number and EAN Code.

CE

Date: May 24,2021

Signature:

A handwritten signature in blue ink, appearing to be "L. A. K.", written over a light blue horizontal line.



Ingo Kumbrink / President

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 stripes; 5m total
4260168225400	100540		K-Tape Lymph Pre-Cut 40cm 12 Stripes; 4,8m total
K-Tape for me			
	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 fo me to for ankle pain 2 Pre-Cuts (1x150mm, 1x300mm)
K-Tape Cut			
4260168226117	100611		K-Tape Cut15 red
4260168226124	100612		K-TapeCut 15 blue
4260168226131	100613		K-TapeCut15 beige
4260168226148	100614		K-Tape Cut15 black
4260168226216	100621		K-TapeCut20 red
4260168226223	100622		K-TapeCut20 blue
4260168226230	100623		K-TapeCut 20 beige
4260168226247	100624		K-TapeCut20 black
4260168226315	100631		K-TapeCut30 red
4260168226322	100632		K-TapeCut30 blue
4260168226339	100633		K-TapeCut30 beige
4260168226346	100634		K-TapeCut30 black