



EC Declaration of Conformity

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

SRN: DE-MF-000005476

(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: biviah 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 10993-1:2021, 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 biviah 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.



Date: April 10, 2024

Signature:

A handwritten signature in blue ink, appearing to read "Ingo Kumbrink".

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			
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-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



K-Tape Team			
4260168228012		100801	Team blue & Red
4260168228029		100802	Team Black & White
4260168228036		100803	Team Green & White
4260168228043		100804	Team Red & White
4260168228050		100805	Team Bue & White
4260168228067		100806	Team Black & White
4260168228074		100807	Team Blue & Orange
4260168228081		100808	Team Organe & White
4260168228098		100809	Team Black & Yellow
4260168228104		100810	Team Yellow & Green
4260168228111		100811	Team Blue & Cyan
4260168228128		100812	Team Blue & Yellow
4260168228135		100813	Team Yellow & Black (box with grey letters)
4260168228142		100814	Team Yellow& Black
4260168228159		100815	Team Orange & Black
4260168228166		100816	Team Red & Blue
4260168228173		100817	Team Red & Yellow
4260168228180		100818	Team Yellow & Blue
4260168228197		100819	Team Red & Black
4260168228203		100820	Team Cyn & Orange
4260168228210		100821	Team Blue & Green
4260168228227		100822	Team Cyan & Magneta
4260168228234		100823	Team Cyan & White
4260168228241		100824	Team Magenta & White
4260168228258		100825	Team Red & Red
4260168228265		100826	Team Orange & Orange
4260168228272		100827	Team Yellow & Yellow
4260168228289		100828	Team White & White
4260168228296		100829	Team Black & Black
4260168228302		100830	Team Blue & Blue
4260168228319		100831	Team Green & Green
4260168228326		100832	Team Cyan & Cyan
4260168228333		100833	Tea Magenta & Magenta

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4260168221211		100121	K-Tape Team Yellow
4260168221228		100122	K-Tape Team Red2
4260168221235		100123	K-Tape Team blue2
4260168221242		100124	K-Tape Team Green
4260168221259		100125	K-Tape Team Orange