

EU-Declaration of Conformity
within the meaning of Regulation (EU) 2017/745 on medical devices

The manufacturer:



**ARGON Medical Production & Vertriebs
Gesellschaft mbH & Co. KG
Franz-Kirsten-Str. 1
DE-55411 Bingen**

EUDAMED - SRN:

DE-MF-000012472

declares as a manufacturer within the meaning of the above-mentioned regulation, places the following group of **class I** medical devices in accordance with Annex VIII of Regulation (EU) 2017/745 on the market:

Transfer Accessories

(UMDNS 16-350 Abform, dental)

According to risk class I, rule 5
(acc. to the attached product list)

The sole responsibility for issuing the declaration of conformity in accordance with **Annex IV** of Regulation (EU) 2017/745 and for ensuring that the design and manufacture of the above-mentioned medical devices comply with the Regulation and national regulations, lies with the above-mentioned company.

The technical documentation according to **Annexes II and III** of Regulation (EU) 2017/745 on medical devices is fully available. The above-mentioned product(s) meet(s) the General Safety and Performance Requirements according to **Annex I** of Regulation (EU) 2017/745. The instructions for use belonging to the product(s) are available. The conformity assessment procedure has been carried out in accordance with **Annex II and III** of the above-mentioned Regulation.

The product(s) comply(s) with the applicable standards and laws, which are documented in the list of applicable standards for this product group in the technical documentation.

This declaration of conformity is valid for 4 years from the date of signature for the products described in the attached product list.

Bingen am Rhein, 07.02.2024

Place, Date

Signature Managing Director

(Richard Donaca)

Annex Declaration of Conformity Transfer Accessories RC 1

Basic UID	UID-01	article number [REF]	product name	Purpose	MDNRs	Risk Class
++EAGN4404B	EAGNAATK400	AA TK40	Transfer Cap for Anatomie Abdoments 4,0mm	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNAATK500	AA TK50	Transfer Cap for Anatomie Abdoments 5,0mm	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNCADSBVA010	CAD_SB_VBA01	CAD Scan Body for VBA & SBA Abdoments	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNCADSB20	CAD_SB2	CAD Scan Body 2mm Post	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNCADSB30	CAD_SB3	CAD Scan Body 3mm Post	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNCGKSPR00	CG_KSPR0	K3Pro Glue Pen for Clou & Vana Base Abdoments 2mm Post	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNCGKSPR00	CG_KSPR0	K3Pro Glue Pen for Clou & Vana Base Abdoments 3mm Post	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNCGKSPR020	CGSB_K3PR02	TriScan Post for K3Pro Ti-Base with 2mm Post - Titanium	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNCGKSPR020	CGSB_K3PR02	TriScan Post for K3Pro Ti-Base with 2mm Post - Titanium	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNCGKSPR02PK0	CGSB_K3PR02 PK	TriScan Post for K3Pro Ti-Base with 2mm Post - Peek	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNCGKSPR02PK0	CGSB_K3PR02 PK	TriScan Post for K3Pro Ti-Base with 2mm Post - Peek	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNCGKSPR02KHDL0	CGSB_K3PR02 K_HDL	TriScan Post for K3Pro Ti-Base with 2mm Post - Titanium short - HDL	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNCGKSPR02KHDL0	CGSB_K3PR02 K_HDL	TriScan Post for K3Pro Ti-Base with 2mm Post - Titanium	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNCGKSPR03AL0	CGSB_K3PR03 AL	TriScan Post for K3Pro Ti-Base with 3mm Post - aluminum	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNCGKSPR03AL0	CGSB_K3PR03 AL	TriScan Post for K3Pro Ti-Base with 3mm Post - aluminum	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNCGKSPR03PK0	CGSB_K3PR03 PK	TriScan Post for K3Pro Ti-Base with 3mm Post - Peek	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNCGKSPR03PK0	CGSB_K3PR03 PK	TriScan Post for K3Pro Ti-Base with 3mm Post - Peek	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNCGKSPR03KHDL0	CGSB_K3PR03 K_HDL	TriScan Post for K3Pro Ti-Base with 3mm Post - Titanium short - HDL	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNCGKSPR03KHDL0	CGSB_K3PR03 K_HDL	TriScan Post for K3Pro Ti-Base with 3mm Post - Titanium	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNCSSP20	CS_SPL2	K3Pro Caric Scan Post 2mm Platform (GH 0.5mm)	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNCSSP20	CS_SPL2	K3Pro Caric Scan Post 2mm Platform (GH 1.5mm)	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNCSSP30	CS_SPL3	K3Pro Caric Scan Post 3mm Platform (GH 0.5mm)	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNCSSP30	CS_SPL3	K3Pro Caric Scan Post 3mm Platform (GH 1.5mm)	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNDLR090	DLR_09	Finder Pro block out spacer	Positioning Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNDLR150	DLR_15	Finder Pro impression post	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNEATK40K0	EA TK40 K	Transfer Cap short for closed tray impression K3Pro 2mm	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNEATK50K0	EA TK50 K	Transfer Cap short for closed tray impression K3Pro 3mm	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNEATK50S0	EA TK50 S	Transfer Cap long for closed tray impression K3Pro Short	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNEAZSK14P0M0	EAZ_SK14P0M	Screw ring POM for Emergence EAZ Abdoments	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNETKPR020	ETK3PR02	Transfer for closed tray impression K3Pro 2mm	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNETKPR020	ETK3PR02	Transfer for closed tray impression K3Pro 2mm - long version	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNETKPR02ALU0	ETK3PR02 ALU	Transfer for closed tray impression K3Pro 2mm - Alu	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNETKPR030	ETK3PR03	Transfer for closed tray impression K3Pro 3mm	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNETKPR030	ETK3PR03	Transfer for closed tray impression K3Pro 3mm - long version	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNETKPR0350	ETK3PR03 S	Transfer for closed tray impression K3Pro Short	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNETKPR03ALU0	ETK3PR03 ALU	Transfer for closed tray impression K3Pro 3mm - Alu	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNETSK3PR02L0	ETS_K3PR02 L	Screw for closed tray impression transfer K3Pro 2mm Well	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNETSK3PR02L0	ETS_K3PR02 L	Screw for closed tray impression transfer K3Pro 3mm Well	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNETSK3PR03L0	ETS_K3PR03 L	Screw for closed tray impression transfer K3Pro Short	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNETSK3PR03L0	ETS_K3PR03 L	Screw for closed tray impression transfer K3Pro Short	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNFLC010	FLC_01	Finder Locator Transfer Capping	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNGAGAH010	GAG_AH01	Cast Cap for UCLA Abdoments	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNGATAX010	GAT_AH01	Cast Cap for GAT and UCLA Abdoments	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNGATSK010	GAT_SK01	Scan Cap for Base Abdoments	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNGT4000201XP20	GT 400020_1XP2	K3Pro XP Impression Post GT GH1,0mm - 1mm sub - 2mm Platform	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNGT4000201XP30	GT 400020_1XP3	K3Pro XP Impression Post GT GH1,0mm - 1mm sub - 3mm Platform	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNGT4000201XP30	GT 400020_1XP3	K3Pro XP Impression Post GT GH1,0mm - 1mm sub - Short Platform	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNGT4000301XP30	GT 400030_1XP3	K3Pro XP Impression Post GT GH2,0mm - 1mm sub - 3mm Platform	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNGT4000302XP20	GT 400030_2XP2	K3Pro XP Impression Post GT GH1,0mm - 2mm sub - 2mm Platform	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNGT4000302XP30	GT 400030_2XP3	K3Pro XP Impression Post GT GH1,0mm - 2mm sub - 3mm Platform	Transfer Accessories	16-350/ Abdruckform, dental	I
++EAGN4404B	EAGNGT4000302XP30	GT 400030_2XP3	K3Pro XP Impression Post GT GH1,0mm - 2mm sub - Short Platform	Transfer Accessories	16-350/ Abdruckform, dental	I

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