

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:

Hand Instruments

(UMDNS 11-160 Dental-Handinstrument)

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 - hand instruments RC1

Basic UDI	UDI-DI	Article number / REF1	Product name	Purpose	INDQS	Risk Class
++EAGN41042	EAGNAAAK3PROZT20	AAA K3PRO.ZT2	Abutment Removal tool for K3Pro 2mm Platform, two-part	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNAAAK3PROZT10	AAA K3PRO.ZT1 L	Abutment Removal tool for K3Pro 2mm Platform, two-part - long	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNAAAK3PROZT30	AAA K3PRO.ZT3	Abutment Removal tool for K3Pro 3mm Platform, two-part	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNAAAK3PROZT3L	AAA K3PRO.ZT3 L	Abutment Removal tool for K3Pro 3mm Platform, two-part - long	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNAAAK3PROZTSHORT0	AAA K3PRO.ZTSHOR	Abutment Removal tool for K3Pro 3mm Platform, two-part - long	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNAAAK3PROZTSHORTL0	AAA K3PRO.ZTSHOR L	Abutment Removal tool for K3Pro 3mm Platform, two-part - long	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNAAAK3PROZT10	AAA K3PRO.Z1	Abutment Removal tool for K3Pro 2mm Well for Ratchet	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNAAAK3PROZ10	AAA K3PRO.Z1 L	Abutment Removal tool for K3Pro 2mm Well for Ratchet - long	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNAAAK3PROZ30	AAA K3PRO.Z3	Abutment Removal tool for K3Pro 3mm Well for Ratchet	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNAAAK3PROZ30L	AAA K3PRO.Z3 L	Abutment Removal tool for K3Pro 3mm Well for Ratchet - long	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNAAAK3PROSHORT0	AAA K3PRO.SHOR	Abutment Removal tool for K3Pro Short Platform for Ratchet	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNAAAP1010	ABP01	Abutment Preparation instrument & Gauge holder	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNAAEHK3PROZ0	AEH K3PRO.Z	Abutment Insertion tool for K3Pro 2mm Platform	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNAAEHK3PROZ30	AEH K3PRO.Z3	Abutment Insertion tool for K3Pro 3mm Platform	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNAAARTPR020	ART PR02	Abutment Removal Tool	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN42045	EAGNBRTK3PRO0	BTS K3PRO	Drill Depthgauge for K3Pro	Gauges	11-160/ Dental-Handinstrument	1
++EAGN42045	EAGNDLR130	DLR_13	Finder Pro angulation measurement tool	Positioning Accessories	11-160/ Dental-Handinstrument	1
++EAGN42045	EAGNDLR160	DLR_16	Finder Pro parallel pin	Positioning Accessories	11-160/ Dental-Handinstrument	1
++EAGN43048	EAGNGSS20	GS_3/2	K3Pro Gingival Height Measure instrument	Gauges	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNGSS140	GS_S_14	Gewindeschneider für K3Pro Schrauben 1,4 mm	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNGSS160	GS_S_16	Gewindeschneider für K3Pro Schrauben 1,6 mm	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNGSS16S0	GS_S_16S	Gewindeschneider für K3Pro Schrauben 1,6 mm Short	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNLAK3PROEH0	LAK3PRO.EH	K3Pro Labort Click Aniling Insertion Instrument	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN42045	EAGNRHHNB0	RHH_NB	Nobel Biocone Reducer Holder	Positioning Accessories	11-160/ Dental-Handinstrument	1
++EAGN42045	EAGNRSRT1RA30350	RSRT_RA3-0-3.5	Rapid Surgery Implantat Bergungsinstrument 4,0 & 3,5mm	Positioning Accessories	11-160/ Dental-Handinstrument	1
++EAGN42045	EAGNRSRT1RA40450	RSRT_RA4-0-4.5	Rapid Surgery Implantat Bergungsinstrument 4,0 & 4,5mm	Positioning Accessories	11-160/ Dental-Handinstrument	1
++EAGN42045	EAGNRSRT1RA50600	RSRT_RA5-0-6.0	Rapid Surgery Implantat Bergungsinstrument 5,0 & 5,0mm	Positioning Accessories	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNDLCI0	DLCI	Finder Pro Universal instrument four-piece	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNDLCP0	DLCI_P	Finder Pro Universal instrument Labor	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN42045	EAGNFLAM10	FLAM1	Finder/ Locator Angulation Measurement Tool	Positioning Accessories	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNFLCI010	FLCI_01	Finder/ Locator Core Instrument	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN42045	EAGNFLP0	FLPP	Finder / Locator Parallel Pin	Positioning Accessories	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNK3PROEH0	K3PRO.EH	K3Pro Click Analing Insertion Instrument	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNK3PROHG0	K3PRO.HG	K3Pro Handring with Thread M6 - red	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNKKEI020	KKEL_02	O-Ring Insertion tool with Ratchet connection	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN42045	EAGNMBL1A0	MBL1A	Multi Base Insertion Sleeve	Positioning Accessories	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNMBHREI230	MBHREI_23	Instrument for Hand/ Ratchet Insertion - XP Multi Base Abutment	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNMBHREI20	MBHREI2	K3Pro Multi Base Instrument for Hand/ Ratchet Insertion - 2mm Platform	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNMBHREI30	MBHREI3	K3Pro Multi Base Instrument for Hand/ Ratchet Insertion - 3mm Platform	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN42045	EAGNMP000	PP_00	K3Pro Parallel Pin 0°	Positioning Accessories	11-160/ Dental-Handinstrument	1
++EAGN42045	EAGNMP100	PP_10	K3Pro Parallel Pin 10°	Positioning Accessories	11-160/ Dental-Handinstrument	1
++EAGN42045	EAGNMP150	PP_15	K3Pro Parallel Pin 15°	Positioning Accessories	11-160/ Dental-Handinstrument	1
++EAGN42045	EAGNMP200	PP_20	K3Pro Parallel Pin 20°	Positioning Accessories	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNRAISOWSA0	RA_ISOWSA	ISO Adaptor with ratchet connection	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNRAEI140	RAEI_14	Implant inserter for 2mm Well with Ratchet Connection	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNRAEI160	RAEI_16	Implant inserter for 2mm Well with Ratchet Connection - long	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNRAEI140	RAEI_14	Implant inserter for 2mm Well with Ratchet Connection - long	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNRAEI160	RAEI_16	Implant inserter for 2mm Well with Ratchet Connection - long	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNRK01VK40	RK01_VK4	Hand Knob Adaptor with Square connection	Non Active Driven Tools	11-160/ Dental-Handinstrument	1
++EAGN42045	EAGNRSLSA0	RS_LA	Guide/Adaptor for Sleeves	Positioning Accessories	11-160/ Dental-Handinstrument	1
++EAGN41042	EAGNRV01K0	RV_01K	Ratchet Extension K3Pro 5mm	Non Active Driven Tools	11-160/ Dental-Handinstrument	1

Revision status	1.0
Creator	QMB
Release	OL
	23.01.2024



++EAGN41042	EAGNRFV01L0	RV_01_L	Ratchet Extension K3Pro 10mm	Non Active Driven Tools	11-160/ Dental-Handinstrument	
++EAGN42045	EAGNSEIZHPR020	SEIZH_PRO2	Centering Sleeve for Screw Removal 2mm Well	Positioning Accessories	11-160/ Dental-Handinstrument	
++EAGN42045	EAGNSEIZHPR030	SEIZH_PRO3	Centering Sleeve for Screw Removal 3mm Well	Positioning Accessories	11-160/ Dental-Handinstrument	
++EAGN41042	EAGNSKD01EL0	SKD01EL	Hex Screwdriver with Ratched Connection - extra lang	Non Active Driven Tools	11-160/ Dental-Handinstrument	
++EAGN41042	EAGNSKD01H0	SKD01H	Hex Screwdriver for hand Insertion - lang	Non Active Driven Tools	11-160/ Dental-Handinstrument	
++EAGN41042	EAGNSKD01K0	SKD01K	Hex Screwdriver with Ratched Connection - short	Non Active Driven Tools	11-160/ Dental-Handinstrument	
++EAGN41042	EAGNSKD01L0	SKD01L	Hex Screwdriver with Ratched Connection - lang	Non Active Driven Tools	11-160/ Dental-Handinstrument	
++EAGN41042	EAGNSKD02H0	SKD02H	Hex Screwdriver for hand Insertion - short	Non Active Driven Tools	11-160/ Dental-Handinstrument	
++EAGN41042	EAGNSKD03H0	SKD03H	Hex Screwdriver for hand Insertion - extra short	Non Active Driven Tools	11-160/ Dental-Handinstrument	
++EAGN41042	EAGNSKD04H0	SKD04H	Hex Screwdriver for hand Insertion - extra Long	Non Active Driven Tools	11-160/ Dental-Handinstrument	
++EAGN43048	EAGNVBARH20	VBA_RH2	RapidFix Abutment/Implant Positioning Guide for 2mm Well	Gauges	11-160/ Dental-Handinstrument	
++EAGN43048	EAGNVBARH30	VBA_RH3	RapidFix Abutment/Implant Positioning Guide for 3mm Well	Gauges	11-160/ Dental-Handinstrument	
++EAGN42045	EAGNVBABS010	VBA_BS_01	K3Pro RapidFix Drill guide	Positioning Accessories	11-160/ Dental-Handinstrument	
++EAGN41042	EAGNVBARHRE230	VBA_HREI2_3	K3Pro RapidFix Instrument for Hand/ Ratched Insertion	Non Active Driven Tools	11-160/ Dental-Handinstrument	