

	EC Declaration of Conformity Council Directive 93/42/EEC Annex II, incl. section 4	Doc. No.: DCE-AH01-A21.04
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We, the manufacturer

aap Joints GmbH,
Wilhelm-von-Siemens-Strasse 23, Aufgang F,
12277 Berlin, Germany

hereby declare under our sole responsibility, that the medical devices specified below fulfil the obligations of Council Directive 93/42/EEC and meet the relevant Essential Requirements of Annex I of aforementioned directive.

Product Group:	Hip Joint Replacement Implants
Product:	VarioLoc Hip System
Catalog Numbers:	see Annex 1 – Product list
Classification:	Class III (according to Rule 8, 93/42/EEC and Article 1, 2005/50/EC on the reclassification of hip, knee and shoulder joint replacement)
Conformity assessment route:	Annex II, EC Declaration of Conformity (Full quality assurance system) including section 4, 93/42/EEC
Certifications:	EC Certificate: CE-MDD-0058/09/2019/01 Design Examination Certificate: CE-MD-0058/09/2019/01/DD.02 ISO 13485:2016 Certificate: ISO.Med.0058.09.2019
Applied standards:	ISO 13485:2016; EN ISO 14971:2019; EN 556-1:2001; EN 62366-1:2015/A1:2020; ISO 10993-1:2018; EN ISO 10993-3:2014; EN ISO 10993-5:2009; ISO 10993-6:2016; ISO 10993-7:2008/A1:2019; ISO 10993-10:2010; ISO 10993-11:2017; EN 1041:2008/A1:2013; EN 15223-1:2016; ISO 11135:2014/A1:2018; ISO 11137-1:2006/A2:2018; ISO 11137-2:2015; ISO 11607-1:2019; ISO 11607-2:2019; ISO 14630:2012; EN ISO 21534:2009; EN ISO 21535:2009

All supporting documentation is retained under the premises of the manufacturer. The compliance with the requirements is controlled by:

Notified Body: Notice Belgelendirme, Muayene ve Denetim Hizmetleri A.Ş.
Esentepe Mahallesi Milangaz Caddesi No:75 A/92
Kartal/İstanbul, Istanbul

NB identification number: 2764

This declaration of conformity is valid until 26.May 2024.

Berlin, 24. May 2021

Signature:



Name:

Feipeng Huang

Position:

Managing Director



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Annex 1 - Product List

VarioLoc Stem TPS Coating		GMDN Code: 60516
Catalog #	Description	Size
A1101-0-1050	VarioLoc Stem, TPS Coating, STD	5mm
A1101-0-1060	VarioLoc Stem, TPS Coating, STD	6mm
A1101-0-1075	VarioLoc Stem, TPS Coating, STD	7.5mm
A1101-0-1090	VarioLoc Stem, TPS Coating, STD	9mm
A1101-0-1100	VarioLoc Stem, TPS Coating, STD	10mm
A1101-0-1110	VarioLoc Stem, TPS Coating, STD	11mm
A1101-0-1125	VarioLoc Stem, TPS Coating, STD	12.5mm
A1101-0-1135	VarioLoc Stem, TPS Coating, STD	13.5mm
A1101-0-1150	VarioLoc Stem, TPS Coating, STD	15mm
A1101-0-1160	VarioLoc Stem, TPS Coating, STD	16mm
A1101-0-1175	VarioLoc Stem, TPS Coating, STD	17.5mm
A1101-0-1200	VarioLoc Stem, TPS Coating, STD	20mm
A1101-0-2075	VarioLoc Stem, TPS Coating, LAT	7.5mm
A1101-0-2090	VarioLoc Stem, TPS Coating, LAT	9mm
A1101-0-2100	VarioLoc Stem, TPS Coating, LAT	10mm
A1101-0-2110	VarioLoc Stem, TPS Coating, LAT	11mm
A1101-0-2125	VarioLoc Stem, TPS Coating, LAT	12.5mm
A1101-0-2135	VarioLoc Stem, TPS Coating, LAT	13.5mm
A1101-0-2150	VarioLoc Stem, TPS Coating, LAT	15mm
A1101-0-2160	VarioLoc Stem, TPS Coating, LAT	16mm
A1101-0-2175	VarioLoc Stem, TPS Coating, LAT	17.5mm
A1101-0-2200	VarioLoc Stem, TPS Coating, LAT	20mm

Femoral Head		GMDN Code: 33175
Catalog #	Description	Size
A1100-9-2201	Femoral Head, CoCrMo	22mm,-3mm
A1100-9-2202	Femoral Head, CoCrMo	22mm,+0mm
A1100-9-2801	Femoral Head, CoCrMo	28mm,-3.5mm
A1100-9-2802	Femoral Head, CoCrMo	28mm,+0mm
A1100-9-2803	Femoral Head, CoCrMo	28mm,+3.5mm
A1100-9-2804	Femoral Head, CoCrMo	28mm,+7mm
A1100-9-2805	Femoral Head, CoCrMo	28mm,+10.5mm
A1100-9-3201	Femoral Head, CoCrMo	32mm,-4mm
A1100-9-3202	Femoral Head, CoCrMo	32mm,+0mm
A1100-9-3203	Femoral Head, CoCrMo	32mm,+4mm
A1100-9-3204	Femoral Head, CoCrMo	32mm,+7mm
A1100-9-3205	Femoral Head, CoCrMo	32mm,+10.5mm

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Femoral Head		GMDN Code: 33175
Catalog #	Description	Size
A1100-9-3601	Femoral Head, CoCrMo	36mm,-4mm
A1100-9-3602	Femoral Head, CoCrMo	36mm,+0mm
A1100-9-3603	Femoral Head, CoCrMo	36mm,+4mm
A1100-9-3604	Femoral Head, CoCrMo	36mm,+8mm
A1100-9-3605	Femoral Head, CoCrMo	36mm,+10.5mm

VarioCup, TPS Coating		GMDN Code: 60516
Catalog #	Description	Size
A1402-0-1042	VarioCup, TPS Coating, No-hole	42mm, BB
A1402-0-1044	VarioCup, TPS Coating, No-hole	44mm, MM
A1402-0-1046	VarioCup, TPS Coating, No-hole	46mm, NN
A1402-0-1048	VarioCup, TPS Coating, No-hole	48mm, OO
A1402-0-1050	VarioCup, TPS Coating, No-hole	50mm, PP
A1402-0-1052	VarioCup, TPS Coating, No-hole	52mm, PP
A1402-0-1054	VarioCup, TPS Coating, No-hole	54mm, QQ
A1402-0-1056	VarioCup, TPS Coating, No-hole	56mm, QQ
A1402-0-1058	VarioCup, TPS Coating, No-hole	58mm, RR
A1402-0-1060	VarioCup, TPS Coating, No-hole	60mm, RR
A1402-0-1062	VarioCup, TPS Coating, No-hole	62mm, SS
A1402-0-1064	VarioCup, TPS Coating, No-hole	64mm, SS
A1402-0-1066	VarioCup, TPS Coating, No-hole	66mm, TT
A1402-0-1068	VarioCup, TPS Coating, No-hole	68mm, TT
A1402-0-2042	VarioCup, TPS Coating, Three-hole	42mm, BB
A1402-0-2044	VarioCup, TPS Coating, Three-hole	44mm, MM
A1402-0-2046	VarioCup, TPS Coating, Three-hole	46mm, NN
A1402-0-2048	VarioCup, TPS Coating, Three-hole	48mm, OO
A1402-0-2050	VarioCup, TPS Coating, Three-hole	50mm, PP
A1402-0-2052	VarioCup, TPS Coating, Three-hole	52mm, PP
A1402-0-2054	VarioCup, TPS Coating, Three-hole	54mm, QQ
A1402-0-2056	VarioCup, TPS Coating, Three-hole	56mm, QQ
A1402-0-2058	VarioCup, TPS Coating, Three-hole	58mm, RR
A1402-0-2060	VarioCup, TPS Coating, Three-hole	60mm, RR
A1402-0-2062	VarioCup, TPS Coating, Three-hole	62mm, SS
A1402-0-2064	VarioCup, TPS Coating, Three-hole	64mm, SS
A1402-0-2066	VarioCup, TPS Coating, Three-hole	66mm, TT
A1402-0-2068	VarioCup, TPS Coating, Three-hole	68mm, TT

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VarioCup, insert, Highly cross-linked UHMWPE		GMDN Code: 43168
Catalog #	Description	Size
A1403-2-2242	VarioCup insert, Neutral, Highly cross-linked UHMWPE	22mm ID, BB
A1403-2-2244	VarioCup insert, Neutral, Highly cross-linked UHMWPE	22mm ID, MM
A1403-2-2842	VarioCup insert, Neutral, Highly cross-linked UHMWPE	28mm ID, BB
A1403-2-2844	VarioCup insert, Neutral, Highly cross-linked UHMWPE	28mm ID, MM
A1403-2-2846	VarioCup insert, Neutral, Highly cross-linked UHMWPE	28mm ID, NN
A1403-2-2848	VarioCup insert, Neutral, Highly cross-linked UHMWPE	28mm ID, OO
A1403-2-2850	VarioCup insert, Neutral, Highly cross-linked UHMWPE	28mm ID, PP
A1403-2-2854	VarioCup insert, Neutral, Highly cross-linked UHMWPE	28mm ID, QQ
A1403-2-2858	VarioCup insert, Neutral, Highly cross-linked UHMWPE	28mm ID, RR
A1403-2-2862	VarioCup insert, Neutral, Highly cross-linked UHMWPE	28mm ID, SS
A1403-2-3248	VarioCup insert, Neutral, Highly cross-linked UHMWPE	32mm ID, OO
A1403-2-3250	VarioCup insert, Neutral, Highly cross-linked UHMWPE	32mm ID, PP
A1403-2-3254	VarioCup insert, Neutral, Highly cross-linked UHMWPE	32mm ID, QQ
A1403-2-3258	VarioCup insert, Neutral, Highly cross-linked UHMWPE	32mm ID, RR
A1403-2-3262	VarioCup insert, Neutral, Highly cross-linked UHMWPE	32mm ID, SS
A1403-2-3654	VarioCup insert, Neutral, Highly cross-linked UHMWPE	36mm ID, QQ
A1403-2-3658	VarioCup insert, Neutral, Highly cross-linked UHMWPE	36mm ID, RR
A1403-2-3662	VarioCup insert, Neutral, Highly cross-linked UHMWPE	36mm ID, SS
A1403-2-3666	VarioCup insert, Neutral, Highly cross-linked UHMWPE	36mm ID, TT
A1403-3-2242	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	22mm ID, BB
A1403-3-2244	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	22mm ID, MM
A1403-3-2842	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	28mm ID, BB
A1403-3-2844	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	28mm ID, MM
A1403-3-2846	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	28mm ID, NN
A1403-3-2848	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	28mm ID, OO
A1403-3-2850	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	28mm ID, PP
A1403-3-2854	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	28mm ID, QQ
A1403-3-2858	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	28mm ID, RR
A1403-3-2862	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	28mm ID, SS
A1403-3-3248	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	32mm ID, OO
A1403-3-3250	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	32mm ID, PP
A1403-3-3254	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	32mm ID, QQ
A1403-3-3258	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	32mm ID, RR
A1403-3-3262	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	32mm ID, SS
A1403-3-3654	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	36mm ID, QQ
A1403-3-3658	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	36mm ID, RR

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VarioCup, insert, Highly cross-linked UHMWPE		GMDN Code: 43168
Catalog #	Description	Size
A1403-3-3662	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	36mm ID, SS
A1403-3-3666	VarioCup insert, 15° hooded, Highly cross-linked UHMWPE	36mm ID, TT