

	EC Declaration of Conformity Council Directive 93/42/EEC Annex II, incl. section 4	Doc. No.: DCE-AH04-A21.03
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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:	Ceramic Hip Prosthesis
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.04 ISO 13485:2016 Certificate: ISO.Med.0058.09.2019
Applied standards:	ISO 13485:2016; EN ISO 14971:2019; EN 556-1:2001; ISO 10993-1:2018, EN ISO 10993-3:2014; EN ISO 10993-5:2009; ISO 10993-6:2016; ISO 10993-10:2010; ISO 10993-11:2017; EN 62366-1:2015; EN 1041:2008/A1:2013; EN 15223-1:2016; EN ISO 11137-1:2015; EN ISO 11137-2:2015; EN ISO 11137-3:2017; EN ISO 11737-1:2018; EN ISO 11737-2:2009; 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

Ceramic Head		GMDN Code: 38156
Catalog #	Description	Size
A1100-8-2801	Ceramic Head	28mm, -3.5mm
A1100-8-2802	Ceramic Head	28mm, +0mm
A1100-8-2803	Ceramic Head	28mm, +3.5mm
A1100-8-3201	Ceramic Head	32mm, -4mm
A1100-8-3202	Ceramic Head	32mm, +0mm
A1100-8-3203	Ceramic Head	32mm, +4mm
A1100-8-3204	Ceramic Head	32mm, +7mm
A1100-8-3601	Ceramic Head	36mm, -4mm
A1100-8-3602	Ceramic Head	36mm, +0mm
A1100-8-3603	Ceramic Head	36mm, +4mm
A1100-8-3604	Ceramic Head	36mm, +8mm
A1100-8-4001	Ceramic Head	40mm, -4mm
A1100-8-4002	Ceramic Head	40mm, +0mm
A1100-8-4003	Ceramic Head	40mm, +4mm
A1100-8-4004	Ceramic Head	40mm, +8mm

Ceramic Insert		GMDN Code: 48055
Catalog #	Description	Size
A1100-8-2844	Ceramic Insert	28mm ID, MM
A1100-8-2846	Ceramic Insert	28mm ID, NN
A1100-8-3248	Ceramic Insert	32mm ID, OO
A1100-8-3250	Ceramic Insert	32mm ID, PP
A1100-8-3654	Ceramic Insert	36mm ID, QQ
A1100-8-3658	Ceramic Insert	36mm ID, RR
A1100-8-3662	Ceramic Insert	36mm ID, SS
A1100-8-4058	Ceramic Insert	40mm ID, RR
A1100-8-4062	Ceramic Insert	40mm ID, SS
A1100-8-2848	Ceramic Insert	28mm ID, OO
A1100-8-2850	Ceramic Insert	28mm ID, PP
A1100-8-2854	Ceramic Insert	28mm ID, QQ
A1100-8-2858	Ceramic Insert	28mm ID, RR
A1100-8-2862	Ceramic Insert	28mm ID, SS
A1100-8-3254	Ceramic Insert	32mm ID, QQ
A1100-8-3258	Ceramic Insert	32mm ID, RR
A1100-8-3262	Ceramic Insert	32mm ID, SS