

	EC Declaration of Conformity Council Directive 93/42/EEC Annex II, excl. section 4	Doc. No.: DCE-AH21-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 Accessories
Product:	Acetabular Screw, Screw plug, Dome plug
Catalog Numbers:	see Annex 1 – product list
Classification:	Class IIb (according to Rule 8, 93/42/EEC)
Conformity assessment route:	Annex II, EC Declaration of Conformity (Full quality assurance system) excluding section 4, 93/42/EEC
Certifications:	EC Certificate: CE-MD-0058/09/2019/02 ISO 13485:2016 Certificate: ISO.Med.0058.09.2019
Applied standards:	ISO 13485:2016; EN ISO 14971:2019; EN 556-1:2001; EN ISO 10993-1:2018, EN 62366-2008; ISO 10993-5:2009; EN 1041:2008/A1:2013; EN 15223-1:2016; ISO 11135:2014; ISO 11137-1:2006/A2:2018; ISO 11137-2:2015; ISO 11607-1:2019; ISO 11607-2:2006/A1:2014; 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/Istanbul, 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

Cancellous Bone Screw		GMDN Code: 46646
Catalog #	Description	Size
A1103-9-6515	Cancellous Bone Screw	6.5mm, 15mm
A1103-9-6520	Cancellous Bone Screw	6.5mm, 20mm
A1103-9-6525	Cancellous Bone Screw	6.5mm, 25mm
A1103-9-6530	Cancellous Bone Screw	6.5mm, 30mm
A1103-9-6535	Cancellous Bone Screw	6.5mm, 35mm
A1103-9-6540	Cancellous Bone Screw	6.5mm, 40mm
A1103-9-6545	Cancellous Bone Screw	6.5mm, 45mm
A1103-9-6550	Cancellous Bone Screw	6.5mm, 50mm
A1103-9-6555	Cancellous Bone Screw	6.5mm, 55mm
A1103-9-6560	Cancellous Bone Screw	6.5mm, 60mm
A1103-9-6565	Cancellous Bone Screw	6.5mm, 65mm
A1103-9-6570	Cancellous Bone Screw	6.5mm, 70mm

Screw Plug		GMDN Code: 56710
Catalog #	Description	Size
A1103-9-0003	Screw Plug Long	Ø7.4×2.6mm

Dome Plug		GMDN Code: 56710
Catalog #	Description	Size
A1103-9-0001	Dome Plug	Ø7.7×3.5mm