

EC CERTIFICATE

Annex II excluding section 4 of the Directive 93/42/EEC on Medical Devices

Full Quality Assurance System

Certificate Number

CE-MDD-0058/09/2019/02

Manufacturer : aap Joints GmbH

Address : Wilhelm-von-Siemens-Strasse 23, Ausgang F, 12277 Berlin

Product(s) : 1. The hip accessories
- Acetabular screw
- Screw plug
- Dome plug
2. Cement Restrictor and Centralizer
- Cement Restrictor, UHMWPE
- Centralizer, UHMWPE
- Centralizer, PMMA

Model(s) : Please see 2nd page for details of products

Report Number : CE/ISO-MED-0065-09, CE-MED-0108-09

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Validity Date : 2024.05.26

NOTICE, Notified Body 2764, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits. NOTICE must be informed of any significant changes in the design and/or construction of the product(s).

Özlem Vicdan Akdağ
Chairman



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Product Name	Model Name	Size (mm)
The hip accessories -Acetabular screw -Screw plug -Dome plug	Acetabular screw	6,5mm-15mm
		6,5mm-20mm
		6,5mm-25mm
		6,5mm-30mm
		6,5mm-35mm
		6,5mm-40mm
		6,5mm-45mm
		6,5mm-50mm
		6,5mm-55mm
		6,5mm-60mm
		6,5mm-65mm
		6,5mm-70mm
	Screw plug	7,4mmX2,6mm
	Dome plug	7,7mmX3,5mm

Product Name	Model Description	Size(mm)
Cement Restrictor and Centralizer - Cement Restrictor, UHMWPE - Centralizer, UHMWPE - Centralizer, PMMA	Cement Restrictor, UHMWPE	10mm
		12mm
		14mm
		16mm
		18mm
		20mm
	Centralizer, UHMWPE	10mm
		12mm
		14mm
		16mm
		18mm
		20mm
	Centralizer, PMMA	10mm
		12mm
		14mm
		16mm
		18mm
		20mm



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