EU Declaration of Conformity

Manufacturer:

implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Germany

Medical Device(s):

ICARA® Radial Head System

Intended Use:

The modular ICARA® Radial Head System is intended for the treatment of complex radial head fractures and arthritic conditions as a partial replacement for the radial head.

The ICARA® Radial Head is a head intended to replace the partial radial head.
The ICARA® Stem (Stem Component) is a stem for cemented or cementless fixation intended for anchoring the prosthesis in the radius.

REF Number(s):

REF-Numbers see Attachment I - I

Classification:

Class IIb

(Council Directive 93/42/EEC, Annex IX, rule 8, in conjunction with commission directive 2005/50/EC)

Standard(s) applied:

EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971	Medical devices - Application of risk management to medical devices
EN ISO 11137-1	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11135-1	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1	Packaging for terminally sterilized medical devices – Requirements for materials, sterile barrier systems and packaging systems
EN ISO 10993-1	Biological evaluation of medical devices – Part1: Evaluation and testing
EN ISO 14630	Non-active surgical implants - General requirements
EN ISO 21534	Non-active surgical implants - Joint replacement implants - Particular requirements

GMDN code(s) and term(s):

P33701	Elbow radius prosthesis

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We declare under our sole responsibility that the medical device specified above are in conformity with the essential requirements listed in Annex I of Council Directive 93/42/EEC and has been gone through the conformity assessment procedure according to Annex II of Council Directive 93/42/EEC.

Notified Body:	MEDCERT GmbH Pilatuspool 2 20355 Hamburg Germany
EC Certificate of Conformity	Council Directive 93/42/EEC Annex II excluding section 4 Certificate No.: 7092GB410201201A Validity: 01/12/2020 - 27/05/2024

Identification:

CE 0482

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Buxtehude, 04.12.2020
Place, date

i.V. Juliane Höppner
Head of Regulatory Affairs

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Attachment I

Reference number	item description	size	GMDN	GTIN
00700019	ICARA® radial head	Ø19mm	P33701	4048844257231
00700022	ICARA® radial head	Ø22mm	P33701	4048844257248
00701006	ICARA® stem component type 1 cemented	Ø6/35mm	P33701	4048844257255
00701008	ICARA® stem component type 1 cemented	Ø8/35mm	P33701	4048844257262
00701016	ICARA® stem component type 2 cemented	Ø6/35mm	P33701	4048844257279
00701018	ICARA® stem component type 2 cemented	Ø8/35mm	P33701	4048844257286
00701026	ICARA® stem component type S cemented	Ø6/35mm	P33701	4048844279394
00701028	ICARA® stem component type S cemented	Ø8/35mm	P33701	4048844257293
00701106	ICARA® stem component type 1 cemented	Ø6/50mm	P33701	4048844257309
00701108	ICARA® stem component type 1 cemented	Ø8/50mm	P33701	4048844257316
00701116	ICARA® stem component type 2 cemented	Ø6/50mm	P33701	4048844257323
00701118	ICARA® stem component type 2 cemented	Ø8/50mm	P33701	4048844257347
00701126	ICARA® stem component type S cemented	Ø6/50mm	P33701	4048844257354
00701128	ICARA® stem component type S cemented	Ø8/50mm	P33701	4048844257361
00702006	ICARA® stem component type 1 cementless	Ø6/35mm	P33701	4048844257378
00702008	ICARA® stem component type 1 cementless	Ø8/35mm	P33701	4048844257385
00702016	ICARA® stem component type 2 cementless	Ø6/35mm	P33701	4048844257392
00702018	ICARA® stem component type 2 cementless	Ø8/35mm	P33701	4048844257408
00702026	ICARA® stem component type S cementless	Ø6/35mm	P33701	4048844257415
00702028	ICARA® stem component type S cementless	Ø8/35mm	P33701	4048844257422
00702106	ICARA® stem component type 1 cementless	Ø6/50mm	P33701	4048844257439
00702108	ICARA® stem component type 1 cementless	Ø8/50mm	P33701	4048844257446
00702116	ICARA® stem component type 2 cementless	Ø6/50mm	P33701	4048844257453
00702118	ICARA® stem component type 2 cementless	Ø8/50mm	P33701	4048844257460
00702126	ICARA® stem component type S cementless	Ø6/50mm	P33701	4048844257477
00702128	ICARA® stem component type S cementless	Ø8/50mm	P33701	4048844257484

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Attachment II

Reference number	item description	size	GMDN	GTIN
00701006N	ICARA® stem component type 1 cemented TiN	Ø6/35mm	P33701	4048844281892
00701008N	ICARA® stem component type 1 cemented TiN	Ø8/35mm	P33701	4048844280420
00701016N	ICARA® stem component type 2 cemented TiN	Ø6/35mm	P33701	4048844280437
00701018N	ICARA® stem component type 2 cemented TiN	Ø8/35mm	P33701	4048844280444
00701026N	ICARA® stem component type S cemented TiN	Ø6/35mm	P33701	4048844280451
00701028N	ICARA® stem component type S cemented TiN	Ø8/35mm	P33701	4048844280468
00701106N	ICARA® stem component type 1 cemented TiN	Ø6/50mm	P33701	4048844280475
00701108N	ICARA® stem component type 1 cemented TiN	Ø8/50mm	P33701	4048844280482
00701116N	ICARA® stem component type 2 cemented TiN	Ø6/50mm	P33701	4048844280499
00701118N	ICARA® stem component type 2 cemented TiN	Ø8/50mm	P33701	4048844280505
00701126N	ICARA® stem component type S cemented TiN	Ø6/50mm	P33701	4048844280512
00701128N	ICARA® stem component type S cemented TiN	Ø8/50mm	P33701	4048844280529
00702406	ICARA® stem component type 1 cementless HA	Ø6/35mm	P33701	4048844280536
00702408	ICARA® stem component type 1 cementless HA	Ø8/35mm	P33701	4048844280543
00702416	ICARA® stem component type 2 cementless HA	Ø6/35mm	P33701	4048844280550
00702418	ICARA® stem component type 2 cementless HA	Ø8/35mm	P33701	4048844280567
00702426	ICARA® stem component type S cementless HA	Ø6/35mm	P33701	4048844280574
00702428	ICARA® stem component type S cementless HA	Ø8/35mm	P33701	4048844280581
00702506	ICARA® stem component type 1 cementless HA	Ø6/50mm	P33701	4048844280598
00702508	ICARA® stem component type 1 cementless HA	Ø8/50mm	P33701	4048844280604
00702516	ICARA® stem component type 2 cementless HA	Ø6/50mm	P33701	4048844280611
00702518	ICARA® stem component type 2 cementless HA	Ø8/50mm	P33701	4048844280628
00702526	ICARA® stem component type S cementless HA	Ø6/50mm	P33701	4048844280635
00702528	ICARA® stem component type S cementless HA	Ø8/50mm	P33701	4048844280642

End of schedule. No additional information past this point.