

Manufacturer: implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Germany

Medical Device(s): **Intramedullary Plug**

Intended Use: The Intramedullary Plug (non-bioabsorbable) is designed to be inserted into the medullary canal of a bone before bone cement is applied. It is intended for the prevention of cement progression in the diaphysis.

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 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):

P 38799 Polymer orthopaedic cement restrictor, non-bioabsorbable, sterile

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

EU Declaration of Conformity

Attachment I

Reference number	item description	size	GMDN	GTIN
02994000	intramedullary plug	small	P 38799	4048844011147
02994010	intramedullary plug	large	P 38799	4048844011154

End of schedule. No additional information past this point.