EU Declaration of Conformity

Manufacturer:

implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Germany

Medical Device(s):

Trochanter plate for MUTARS® proximal femur revision

Intended Use:

The trochanter plate for MUTARS® proximal femur revision is a sterile, implantable part which is intended to offer a surface laterally on the greater trochanter in order to facilitate a temporary connection of the same to the prosthesis body. The implant serves as a support body for cerclages, which have to be made of different materials in multifilament form, the outer diameter of which is compatible with the implant and have sufficient tensile strength to enable a relatively stable fixation for six weeks.

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 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 46647	Orthopaedic fixation plate, non-bioabsorbable, sterile

Digitally signed by Kojevnikov Dmitrii
Date: 2023.12.08 17:20:35 EET
Reason: MoldSign Signature
Location: Moldova

EU Declaration of Conformity

We declare under our sole responsibility that the medical devices listed in the attachment(s) are in conformity with the essential requirements of Annex I of Council Directive 93/42/EEC and have undergone 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

implantcast GmbH
Lüneburger Schanze 26 D-21614 Buxtehude
Tel.: +49 4161 744-0 Fax: +49 4161 744-200

Buxtehude, 25.05.2021
Place, date

i.V. Juliane Höppner
Head of Regulatory Affairs

EU Declaration of Conformity

Attachment I

Reference number	item description	size	GMDN	GTIN (UDI-DI)
57101302	trochanter plate for MUTARS® proximal femur revision	short	P 46647	04048844506582
57101302S	trochanter plate for MUTARS® proximal femur revision silver	short	P 46647	04048844506599
57101308	trochanter plate for MUTARS® proximal femur revision	long	P 46647	04048844506605
57101308S	trochanter plate for MUTARS® proximal femur revision silver	long	P 46647	04048844506612

End of schedule. No additional information past this point.

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului), Modelul	Denumire comercială (brand)*	Cod GMDN*
1	57101302	57101302 trochanter plate for MUTARS® proximal femur revision Short		P 46647
2	57101308	57101308 trochanter plate for MUTARS® proximal femur revision Long		P 46647

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care deţin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: _ Oxivit Med SRL _____, cu sediul _____ mun.Chisinau, MD-2020, Stradela Studentilor, 6b,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

- Trochanter plate for MUTARS® proximal femur revision

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia *Semnătura* _____

Kojevnikov Dmitrii, director

Data _08/12/2023__