

EU Certificate

Quality Management System

REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I,
Section 2 and 3 and Chapter III



Registration No.: HZ 2068842-1

Manufacturer: **Osteopore International Pte Ltd**
2 Tukang Innovation Grove
#09-06 JTC MedTech Hub
Singapore 618305
Singapore

EUDAMED Single
Registration No.: SG-MF-000011857

Products: Products of class III:

P900402 - STRUCTURES FILLING, REPLACEMENT AND RECONSTRUCTION
DEVICES
RESORBABLE FILLING AND RECONSTRUCTION DEVICES

Intended purpose: Bioresorbable Implants for use in the repair of neurosurgical
burr holes and fresh craniotomy cuts. It is also for use in the augmentation or
restoration of bony contour in the craniofacial skeleton.

Authorised
representative(s): **Obelis S.A.**
Bd. General Wahis, 53, 1030 Brussels, Belgium

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2023-04-12

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 160106921-27

Effective date: 2023-04-12

Expiry date: 2028-04-11

Issue date: 2023-04-12



Rafał Byczkowski
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TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.