

EU Certificate

Technical Documentation Assessment
REGULATION (EU) 2017/745 on Medical Devices,
Annex IX Chapter II, Section 4



Registration No.: IZ 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

General product group
name: P900402 - RESORBABLE FILLING AND RECONSTRUCTION DEVICES
MDN 1102 – Non-active osteo- and orthopaedic implants

Models and types: Osteomesh
Osteoplug
Osteoplug-C

Basic UDI-DI: 888501320PCOSXL8

Classification: III

Intended use: 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.

Product name: Osteopore PCL Scaffolds

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

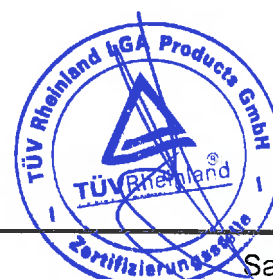
The Notified Body hereby declares that the requirements of Annex IX, Chapter II, Section 4 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and maintains a technical documentation defined by Annex IX, Chapter II, Section 4 of the aforementioned regulation. In addition to this certificate an EU quality management system certificate is required before placing the listed products on the market.

Report No.: 160106921-27

Effective date: 2023-05-08

Expiry date: 2028-04-24

Issue date: 2023-05-08



Sandor Juhasz
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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.

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Certificate history		
Revision:	Description:	Issue date:
0	Initial	2023-04-25
1	Corrected issue date	2023-04-28
2	Corrected expiry date	2023-05-08

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