QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 4-551-135-2106

The NEOEMKI National Medical Device Conformity Assessment and Certification LLC.

as a Certification Body with ID No. NAH-4-0009/2021/K accredited by the National Accreditation Authority for management system certification certifies that the quality management system applied by

BIOCERAMED - Cerâmicos para Aplicações Médicas, S.A.

Head office:

Rua João Francisco do Casal, Armazém 4, Zona Industrial da Taboeira 3800-266 Esgueira, Aveiro – Portugal

Manufacturing site:

Rua José Gomes Ferreira, nº 1 - Armazém D 2660-360 São Julião do Tojal, Loures Portugal

meets the requirements of standard

EN ISO 13485:2016

in the field:

Design and production
of bone grafts, Injectable Bone Substitutes (IBS) and Bone Cements,
and production of calcium phosphate raw materials

Registry number of the related audit report: NE/1081/2021

This certificate is valid until **2024-06-26** supposed that the results of the regular yearly surveillance audits are satisfactory.

Issue: 2

First issued: 2021-06-27

Budapest, 2022-03-16

Laszló Imre Managing Director



EMKI 2815

The authenticity and validity of the certificate are verifiable at NEOEMKI LLC.

neoEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft. neoEMKI National Medical Device Conformity Assessment and Certification LLC.

