

Full Quality Assurance System Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies that the quality assurance system in the organization:

SigmaGraft, Inc. 575 Sally Place, Fullerton CA, 92831, USA

for the design, manufacture and final inspection of medical devices, class III

Bovine xenograft Brand names: InterOss[®], DirectOssTM, Mega-OssTM, MaxxeusTM

complies with requirements of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 2020-06-18 to 2024-05-27

The date of issue of the Certificate: 2020-06-18



Issued under the Contract No. MD-162/2019 Application No: 251/2019 Certificate bears the qualified signature. Warsaw, 18/06/2020 Module H

Anna Wyroba Vice-President