



EC Design Examination Certificate: Certificate ES19/86909.06

Medbone-Medical Devices, Lda

Centro Empresarial Lusoworld II, Rua Pé de Mouro nº26, Linho
2710-335 Sintra, Portugal

Device Identification:

DentOss®TCP

Intended Purpose of Device:

Sterile synthetic ceramic bone graft used for the filling of bone voids or defects of the skeletal system that are not intrinsic to the stability of the bony structure.

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on Medical Devices, Annex II, Section 4

It is certified that the manufacturer's design dossier (and product, where applicable) for the above device has been examined and, based on the evidence submitted, it is considered that the device conforms to the relevant Essential Requirements of EC Directive 93/42/EEC.

This certificate is issued in conjunction with a certificate covering the full quality assurance system to Annex II, which must be subject to satisfactory surveillance audits.

This certificate is valid from 23 June 2020 until 24 May 2024

Issue 1. Certified since 22 April 2010

and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered ES/MAD 228774 dated 08 April 2020

Addenda to that report have been issued on the following dates:

Addendum	Date	Reason for Addendum
	N/A	N/A

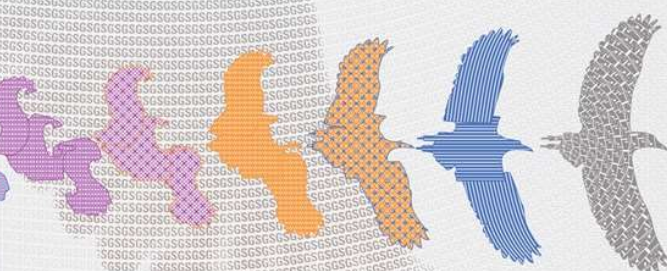
Authorised by

SGS Belgium NV, Notified Body 1639

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