EC Design Examination Certificate: Certificate GB10/80167

Medbone-Medical Devices, Lda

Centro Empresarial, Lusoworld II, Rua Pé de Mouro, nº 26- Linhó,
2710-335, Sintra, Portugal

Device Identification:

Sterile adbone®TCP, adbone® VCP, iceberg® TCP, KimiBone® TCP, SyBone® TCP, EtGraft® TCP, Graftag® TCP, MagiGraft® TCP, BioBone® TCP, MedGraft® TCP, OssGraft® TCP and GTOss®TCP β-TriCalcium Phosphate Bone Grafts.

Intended Purpose of Device:

Sterile synthetic ceramic bone substitute used in 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 19 August 2015 until 22 April 2020
Issue 12

Certification is based on report number(s) GB/PI 222605 dated 20th July 2015

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

Addendum Date	Reason for Addendum
N/A	N/A

Authorised by

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