EC Design Examination Certificate: Certificate GB10/80404

Medbone-Medical Devices, Lda

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

Device Identification:

Sterile adbone® BCP, BioBone® BCP, EtGraft® BCP, MagiGraft® BCP, GTOss® BCP, alfabone® BCP, OssGraft®BCP, QualiOs®BCP and TeeBone®BCP
Biphasic 75% Hydroxyapatite and 25% β-Tri-Calcium Phosphate Ceramic Bone Void Filler

Intended Purpose of Device:

Sterile synthetic ceramic bone substitute used for 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 21 September 2016 until 24 May 2020
Issue 12

Certification is based on report number(s) GB/PI 223989 dated 20 July 2015
Addenda to that report have been issued on the following dates:

Addendum Date	Reason for Addendum
28 August 2015	Change of manufacturer's address
12 October 2015	Change of manufacturer's address
15 September 2016	Addition of new trade names (QualiOs®BCP and TeeBone®BCP)

Authorised by

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