



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 13 07 32283 036

Manufacturer: **Biomatlante SA**
ZA les Quatre Nations
5, Rue Edouard Belin
44360 Vigneux de Bretagne
FRANCE

Product: **Non-Active Implants**
Bone substitute

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.: 713025929

Valid from: 2013-07-24

Valid until: 2017-11-26



Date, 2013-07-26

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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(Devices in Class III)**No. G7 13 07 32283 036****Model(s):**

MBCP™
TRIOSITE™
HATRIC™
MBCP 2000™
TRIBONE 80™
TRICOS™
EUROS-SSBS™
BONE'X™
OpteMx™
4BONE™
SBS60/40®
NUBONE
MBCP+™
TRIOSITE+™
Hydr'Os
H2Bone
SBS H2Bone / SBS H2'Os
VALEOS
BF+®
NEOBONE
Osteoflo
Osteoflo-G
Stimul'Os
BONE X'trudable™
4Bone BCH™

Parameters:

Granules, sticks, blocks,
cylinders, plaquettes,
wedges and cones

Facility(ies):

Biomatlante SA ZA les Quatre Nations
5, Rue Edouard Belin, 44360 Vigneux de Bretagne, FRANCE