ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 16 05 95243 002

Manufacturer: **Bluetens Limited**
Unit 905, 9/F, Kowloon center
33 Ashley road, Tsimshatsui
Kowloon
HONG KONG

EC-Representative: **Bluetens France SAS**
7 passage Saint-Bernard
75011 Paris
FRANCE

Product Category(ies): **TENS**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: 7484029408

Valid from: 2016-08-16
Valid until: 2021-08-15

Date, 2016-08-16

Stefan Preiß

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

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Facility(ies):

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