EC Certificate Full Quality Assurance System: Certificate US15/842371

SGS

The management system of

dBMEDx, Inc.

7761 Shaffer Parkway, Suite 140, Littleton, CO, 80127, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

BBS Revolution Urinary bladder volume measurement ultrasound scanner system.

Where the above scope includes class till medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 16 October 2015 until 16 October 2020 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 28 May 2017 Issue 1, Certified since 16 October 2015

Certification is based on reports numbered WW/MW 606179

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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