EC Certificate Full Quality Assurance System: Certificate KR19/81826331

The management system of

Mcube Technology Co., Ltd.

(HO & Factory1) 39, Magokjungang 12-ro, Gangseo-gu,
Seoul, 07789, Republic of Korea

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

The scope of registration appears on page 2 of this certificate

This certificate is valid from 28 April 2021 until 24 August 2023
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 06 January 2003

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Certification is based on reports numbered WW/PCI 208596

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639
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Mcube Technology Co., Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 2

Detailed scope

**Magnetic Incontinence Therapy System (Model: BioCon-2000W);
Bladder Volume Measurement system
(Model: BioCon-500, BioCon-700, BioCon-900,
BioCon-900S, BioCon-1100).**

Where the above scope includes class III 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.

Additional facilities

(Factory2) #803, 123, Bonghwasan-ro, Jungnang-gu, Seoul, Korea