

The management system of

Bio Medical Technologies Co., Ltd.

(Head Office) 101 Megu BLDG, 21-10 Dongho-ro 15-gil,
Jung-gu, Seoul, 100-452, 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 07 January 2021 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 13 March 2003
and first certified by SGS Belgium NV since 16 December 2019

This is a multi-site certification.

Additional site details are listed on subsequent pages

Certification is based on reports numbered WW/PCI 208711

Authorised by

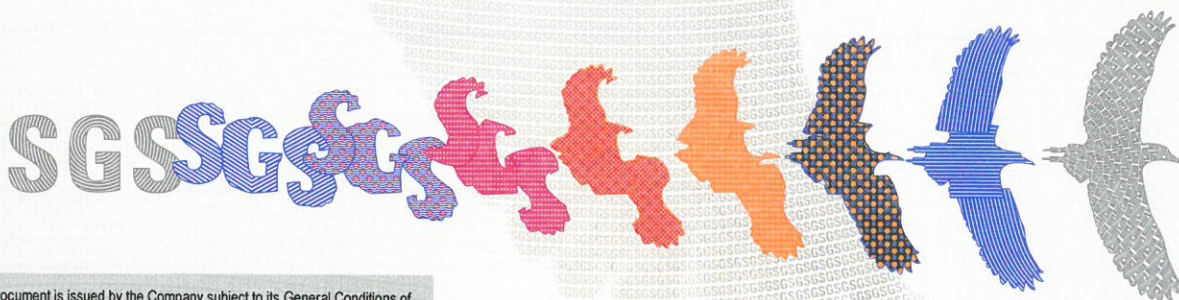


SGS Belgium NV, Notified Body 1639

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LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

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Bio Medical Technologies Co., Ltd.

Directive 93/42/EEC on medical devices, Annex II (excluding section 4)

Issue 2

Detailed scope

“OXIPROBE” brand Oximetric Sensors.

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

(Factory) 112 Hwadong-gil, Gimje-si, Jeollabuk-do, Korea

Bio Medical Technologies Co., Ltd.

(Head Office) 101 Megu BLDG, 21-10 Dongho-ro 15-gil,
Jung-gu, Seoul, 100-452, Korea

Scope:

"OXIPROBE" brand Oximetric Sensors

This corrigendum is only valid together with accompanying 93/42/EEC certificate
Issue 3

Correction Date	Correction
Change approved by SGS on 11 November 2021	(Head Office) 201, 39-12 Hangang-daero 40-gil, Yongsan-gu, Seoul, Republic of Korea (post code 04382)

Authorised by



Global Medical Devices Certification Manager

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LPMD5105 – Corrigendum to Certificate

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SGS Belgium NV

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