EU Quality Management System Certificate KR23/00000132

The management system of

InBody Co., Ltd.

(Factory) 15, Heugam-gil, Ipjang -myeon, Seobuk-gu, Cheonan-si, Chungcheongnam-do, 31025, Korea
SRN: KR-MF-000011833

has been assessed and certified as meeting the requirements of

MDR EU Quality Management System certificate (Annex IX QMS)

For the following products
The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 08 January 2024 until 09 August 2028 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 09 February 2028

Issue 2. Certified since 09 August 2023
Certified activities performed by additional sites are listed on subsequent pages.

Authorised by
Virginie Siloret
Global Medical Device Certification Manager

SGS Belgium NV NB 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 - www.sgs.com

InBody Co., Ltd.

MDR EU Quality Management System certificate (Annex IX QMS)

Class IIa - MDA0204, MDS1009, MDS1010
Bioelectrical Impedance Analyser for monitoring and analysing body composition in obese people and body water management in edema or ascite patients with kidney disease, lymph-edema, liver disease and assessing nutritional status
InBody770 - Basic UDI-DI : 880920959C7YC
BWA ON - Basic UDI-DI : 880920959M3Z2
BWA2.0 - Basic UDI-DI : 880920959I3YN
InBodyH20/H20Ⓑ - Basic UDI-DI : 880920959G5YL
CHA1.0 - Basic UDI-DI : 880920959P5ZF
InBody120 - Basic UDI-DI : 880920959F3YD
InBody270/260/470 - Basic UDI-DI : 880920959F9YR
InBody380 - Basic UDI-DI : 880920959P9ZP
InBody580 - Basic UDI-DI : 880920959R6ZP
InBody970 - Basic UDI-DI : 880920959I4YQ
InBody S10 - Basic UDI-DI : 88092095983X6
InBody370S - Basic UDI-DI : 880920959I5FW

Class IIa - MDA0203, MDS1009, MDS1010
Blood Pressure Monitor
BPBIO320, BPBIO320n - Basic UDI-DI : 880920959F2YB
BP170, BP170B, BP160, BP160B - Basic UDI-DI : 880920959L5Z3
BPBIO220, BPBIO210 - Basic UDI-DI : 880920959K6Z2
BPBIO250 - Basic UDI-DI : 880920959K9Z8
BPBIO320S, BPBIO330, BPBIO330n, BPBIO330S - Basic UDI-DI : 880920959F2YB
BPBIO750 - Basic UDI-DI : 880920959H2YH

Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to NB1639@sgs.com.

Limitation:
N/A

Certification is based on following reports: - WW/PCI/200385 - CTC 1.8
Authorized representative Name and address (if relevant): InBody Europe B.V. Gyroscoopweg 122, 1042 AZ, Amsterdam, The Netherlands

Previous certificate number: N/A
Change in between this certificate and previous one: New variants are added and the change the basic UDI-DI as per the approved Change form

InBody Co., Ltd.

MDR EU Quality Management System certificate (Annex IX QMS)

Issue 2
Sites
InBody Co., Ltd. (Factory) 15, Heugam-gil, Ipjang -myeon, Seobuk-gu, Cheonan-si, Chungcheongnam-do, 31025, Korea
InBody Co., Ltd. (Head office) InBody Bldg., 625, Eonju-ro, Gangnam-gu, Seoul, 06106, Korea
InBody Co., Ltd. (Factory2) 330, Yeongok-gil, Ipjang-myeon, Seobuk-gu, Cheonan-si, Chungcheongnam-do, 31026, Korea