EC CERTIFICATION

EU Quality Management System Certificate

Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

MediBeacon Inc.

425 N. New Ballas Road, Suite 100, St. Louis, Missouri, 63141, United States

Manufacturer SRN: US-MF-000051683

Authorised Representative:

MedEnvoy Global BV [EN]

33, Prinses Margrietplantsoen, 2595 AM, The Hague, Netherlands

Scope:

Monitoring Devices

Certificate Number:
28620241151

Revision:
00

Initial Certification Date:
26 March 2026

Certificate Decision Date:
26 March 2026

Certificate Issue Date:
26 March 2026

Certificate Expiry Date:
9 August 2030

Mikael Hagelin
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

PRODUCT LIST FOR CERTIFICATE

See attached product list

EXAMINATION AND TESTS PERFORMED

Audit report reference	**Stage 1 - ACTY-2024-218453**
	Stage 2 - ACTY-2024-218457
	TD00483-001

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

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CERTIFICATE HISTORY

CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620241151	26 March 2026	Initial certificate

PRODUCT LIST FOR CERTIFICATE

Issued to: MediBeacon Inc.

Certificate number: 28620241151

Certificate valid from: 2026-03-26

Product list issue date:
26 March 2026

Product	Classification and EMDN	Intended use[1]	Date Added
Monitoring Devices			
Basic UDI-DI: 08600083871MB1000HU			
MB1000 - TGFR Monitor Monitor *MediBeacon® Transdermal GFR Measurement System (TGFR)*	Class IIa V0399		2026-03-26
Basic UDI-DI: 08600083871S200GW			
S200 - TGFR Sensor Reusable sensor *MediBeacon® Transdermal GFR Measurement System (TGFR)*	Class IIa V0399		2026-03-26

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[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

MDR QMS Certificate (DOC-1853) Ver. 0

Approved By:

Kallen Withers - Author

March 30, 2026 9:16 AM CDT 8cc89a3c-82d2-4a07-945c-a26f0246cdc4

Version History:

Author	Effective Date	Ver.	Status
Kallen Withers	March 30, 2026 9:16 AM CDT	0	Published