EU Quality Management Certificate

This is to certify that the company

Labtech Kft

Vág u. 4
4031 Debrecen
Hungary

SRN: HU-MF-000002846 and HU-PR-000040167

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	31623209 MDR2017Q
Certificate ID	1000202833
Effective date	2026-04-30
Expiry date	2031-04-29
Frankfurt am Main,	2026-04-30

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
BS-MDR-094

DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director

Annex to EU Quality Management Certificate
SRN of Manufacturer: HU-MF-000002846 and HU-PR-000040167
Certificate ID: 1000202833

Device categories and variants covered by this certificate according to Article 52:

Device category:	**MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**
Product name:	EC type Resting and stress ECG Systems (Product types: EC-12R V6, EC-12S V6, EC-12R/S V6, EC-12RM V6, EC-3S V6, EC-3R/S V6)
Risk classification:	IIa
Basic-UDI-DI:	5999883490ECGSRY
Intended purpose:	The EC type Resting and stress ECG Systems are indicated for: - Recording and analysing multichannel resting electrocardiograms (ECG) in patients 1 year of age and older - Recording and analysing stress/exercise electrocardiograms in patients 1 year of age and older during supervised testing - Simultaneous non-invasive measurement of blood pressure with ECG recording in patients 12 years of age and older using auscultatory method (oscillometric method for telemedicine ECG devices) - Digital display and processing of cardiac electrical activity to assist physicians in assessing cardiac physiology The devices are intended for use by trained healthcare professionals in clinical settings, and emergency medical services. The interpretive statements provided by the device are advisory only and do not replace clinical judgment.

Annex to EU Quality Management Certificate
SRN of Manufacturer: HU-MF-000002846 and HU-PR-000040167
Certificate ID: 1000202833

Device category:	**MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**
Product name:	EC Type Holter Systems (Product types: EC-2H Recorder, EC-2H System, EC-3H Recorder, EC-3H System, EC-12H Recorder, EC-12H System, EC-ABP V6 Recorder, EC-ABP V6 System, EC-3H/ABP V6 Recorder, EC-3H/ABP V6 System, EC-12H/ABP V6 Recorder, EC-12H/ABP V6 System)
Risk classification:	IIa
Basic-UDI-DI:	5999883490HOLTERSR9
Intended purpose:	The EC Type Holter Systems are indicated for: - Continuous ambulatory electrocardiogram (ECG) recording and analysis in patients 1 year of age and older using 2, 3, or 12-channel configurations for detection and analysis of cardiac arrhythmias during daily activities - Continuous ambulatory blood pressure monitoring (ABPM) in patients 12 years of age and older using oscillometric measurement method for diagnosis and management of hypertension and blood pressure disorders - Combined ECG and ABPM monitoring in patients 12 years of age and older for comprehensive cardiovascular assessment during ambulatory conditions - Long-term cardiac monitoring for periods ranging from 24 hours to 14 days to capture intermittent cardiac events and circadian blood pressure patterns - Digital recording, storage, and wireless transmission of cardiac electrical activity and blood pressure data to assist cardiologists in assessing cardiovascular physiology and pathology The devices are intended for use by trained healthcare professionals, including cardiologists, in clinical settings and for supervised home monitoring applications. The recorded data requires analysis using dedicated software by qualified medical professionals for diagnostic interpretation. The interpretive statements provided by the device are advisory only and do not replace clinical judgment.

Annex to EU Quality Management Certificate
SRN of Manufacturer: HU-MF-000002846 and HU-PR-000040167
Certificate ID: 1000202833

Examinations and tests performed:
31623209 A215930MED dated 2025-08-06
31623209 A215931MED EC type Holter systems dated 2026-03-03

Further conditions for or limitations to the validity of the certificate:
n/a

Reference to previous certificates:

Version	Date of Issue	Certificate-ID	Description of change
n/a	n/a	n/a	n/a