LABTECH

DECLARATION OF CONFORMITY
QUALITY CERTIFICATE and CERTIFICATE OF ORIGIN

31 01 2023

Labtech Kft. (4031 Debrecen, Vág út 4, Hungary), as the manufacturer of the noninvasive cardiologic measuring equipment classified as **Class IIa** (according to Annex IX Rule 10 of the 93/42/EEC directive) including:

EC type Holter systems with 'CARDIOSPY' software including:
EC-2H, EC-3H, EC-12H, EC-ABP, EC-3H/ABP models

EC type Holter Systems recorders including:
EC-2H, EC-3H, EC-12H, EC-ABP, EC-3H/ABP models

and

EC type resting and stress Test ECG systems with 'CARDIOSPY' software including:
EC-12R, EC-12RM, EC-12S, EC-12R/S, EC-3RT, EC-12RT, EC-12LT models

EC type resting and stress Test ECG recorders including:
EC-12R, EC-12RM, EC-12S, EC-12R/S, EC-3RT, EC-12RT, EC-12LT models

hereby states that the country of origin of the medical devices is Hungary. The devices and all the accessories meet the requirements of the **Article 120** of the Regulation (EU) 2017/745 of the European Parliament and of the Council (**MDR**) regarding the Transitional provisions for the legacy devices certified based on 93/42/EEC directive and those of below listed international standards:

EN60601-1:2006 + A1:2013 + A12:2014
EN 60601-1-2:2015
EN 60601-1-6:2010
EN 80601-2-30:2010/A1:2015
EN 60601-2-25:1995
EN 60601-2-51:2003
EN 60601-2-47:2001 and AAMI / ANSI / ISO 60601-2-47:2012
EN ISO 15223-1:2016
EN 62304:2006
EN 62366:2008
Serial number:
22103115

The quality management system of Labtech Kft. meets
the **ISO 13485:2016** (Certificate No.: 4-550-135-2106) standard requirements,
and the noninvasive cardiologic measuring equipments
are entitled to bear the **"CE" mark** (Certificate No.: 5-850-200-1806)
The attesting certificates were issued by the
NEOEMKI National Medical Device Conformity Assessment and Certification LLC (1011),
(H-1097 Budapest, Albert Flórián út 3/a., Telephone: +36 20 268 7595)
www.neoemki.hu

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QUALITY AND EFFICIENCY SINCE 1990

DEVELOPMENT AND MANUFACTURE