EC CERTIFICATE

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

No. 5-924-200-2105

The **NEOEMKI National Medical Device Conformity Assessment and Certification LLC.** certifies that the manufacturer:

MyWIWE DIAGNOSZTIKA Kft.
Faiskola út 5.
3300 Eger
Hungary

for the products / product category:

WIWE cardiac diagnostic device family

DSW0001-0000: WIWE cardiac diagnostic device, white
DSW0002-0000: WIWE cardiac diagnostic device, black

applies a quality system which meets the requirements of Directive 93/42/EEC concerning medical devices, Annex II.

Registry number of the related audit report is **NE/1096/2021**. The assessment was based on a remote audit.

This certificate is valid until **2024-05-26** supposed that the remote audit is followed by a successful on-site audit in 6-12 months and the results of the regular yearly surveillance audits are satisfactory.

Issued by NEOEMKI LLC as a Notified Body with identification number **1011**.

Budapest, 2021-05-20

László Imre
Managing Director

NEOEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.

EMKI 2742

The authenticity and validity of the certificate are verifiable at NEOEMKI LLC.