Imed International Medical Equipment Developing Co.Ltd.
H-1119 Budapest, Etele út 59-61. HUNGARY
Tel./Fax: +36 1 481 1372, Mobil tel.: +36 20 9416 758
E-mail: imed@imed.hu Web: www.imed.hu

KONFORMITÄTSERKLÄRUNG

PRODUKT IDENTIFIKATION		
Produktname	Modell/Type	Serielle Nummer
CARDIAX PC Elektrokardiograph	USB Modell	SN ……..

HERSTELLER			
Name	Adresse	Vertreter	Qualitäts-Management System
IMED Kft	Etele út 59-61. H-1119 Budapest, Ungarn	László Bölcsföldi	Zertifiziert nach EN ISO 13485

REGISTRATION INFORMATION		
Benannte Stelle	CE Registrationnummer	Datum der Genehmigung
OGYÉI - EMKI (**CE 1011**) Zrínyi utca 3. H-1051 Budapest, Ungarn	5-833-500-1803	11.03.2018.

KONFORMITÄTSBEWERTUNGSVERFAREN	
Einordnung des Gerätes	Verfahren
Klasse IIa	Annex V von MDD 93/42 EWG

IMED Kft erklärt, dass das oben genannte Medizinprodukt allen Anforderungen der Richtlinie 93/42/EWG und den harmonisierten Normen, die in der Technischen Dokumentation aufgelistet sind, entspricht.

In Vertretung der Hersteller: László Bölcsföldi

IMED Kft. 1119 Bp. Etele út 59-61. Tel/Fax: +36 1 481-1372 Adószám: 10487287-2-43

Funktion: Geschäftsführer Unterschrift:

Ort, Datum: Budapest, 23.05.2022.

Imed Ltd. H-1119 Budapest, Etele út 59-61. Hungary
Phone: +36 1 481 1372, Mobile phone: +36 20 9416 758
E-mail: imed@imed.hu Web: www.imed.hu

MANUFACTURER'S DECLARATION IN REGARDS TO REGULATION 2023/607

with respect to the certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD), (Directive Certificates) and their validity per Article 120.2 of Regulation (EU) 2017/745 on Medical Devices as amended by Regulation (EU) 2023/607 of 20 March 2023 (MDR)
and with respect to the devices' and their manufacturer's compliance with the conditions to continued placing on the market or putting into service per Article 120.3c of the MDR:

Manufacturer name	IMED Ltd.
Manufacturer address	1119 Budapest, Etele ut 59-61. Hungary
Single Registration Number (SRN)	HU-MF-000015964

Notified body name	NEOEMKI Kft.
Notified body number	CE 1011
Directive certificate number to which this confirmation is made	5-833-500-1803
Date of validity as indicated on the Directive certificate	20 March 2023
End date of extended validity/ transition period	26 September 2024

Device name	CARDIAX PC Based ECG System
Device class	IIa

We, as the manufacturer declare under our sole responsibility:

for the above listed Directive certificate the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and the above listed device and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- Directive certificate covering the listed device was issued after 25 May 2017, was valid 26 May 2021, was not withdrawn by 20 March 2023, and did expire before 20 March 2023 before its date of expiry, on 22 February 2023, we concluded a written contract with the notified body SGS Belgium NV (CE 1639) regarding

the conformity assessment of the above device in accordance with Section 4.3, second subparagraph, of Annex VII MDR.

❖ The device continues to comply with the MDD.

❖ The device has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.

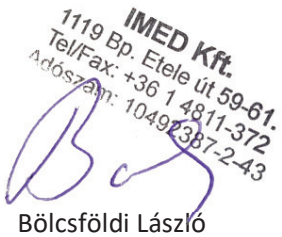
❖ The device do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

❖ IMED Ltd. undertakes that by 26 May 2024 at the latest, its quality management system will comply with the provisions of Article 10 (9) of the MDR.

❖ We acknowledge that requirements relating to post-market surveillance, vigilance, registration of economic operators and of devices in accordance with MDR apply for the device family/ies as listed in the attached schedule.

❖ On 20 April 2023 IMED Ltd. concluded a written contract with NEOEMKI Kft. regarding the supervision of the MDD certificate.

Signed for and on behalf of the manufacturer:



Bölcsföldi László
general manager

Budapest, 25 April 2023

MESA Medizintechnik GmbH
Schärflmühlweg 4
D-83671-Benediktbeuern
Tel/Phone: +49-8857-6918-0
Fax: +49-8857-6918-29

EG-Konformitätserklärung
EC-Declaration of Conformity

EG-Konformitätserklärung für Medizinprodukte
nach MDR (EU) 2017/45, Artikel 19, Anhang IV
EC-Declaration of Conformity for medical products
in accordance to MDR (EU) 2017/745, Article 19, Annex IV

Hersteller und Bevollmächtigter / SRN:
Manufacturer and authorized representative / SRN:

MESA Medizintechnik GmbH SRN DE-MF-000006808

Wir erklären in alleiniger Verantwortung, dass die nachstehenden Medizinprodukte:
We declare on our own responsibility, that the listed medical products below:

Geräteart / Product	Patienten-Daten-Management-Software-System, Patient-Data-Management-Software-System
Bezeichnung / Type	DDC digital Diagnostic Center Ver. 3.0.0.0
REF	DDC-10010
UDI	(01)4260336660064(10)3.0.0.0(11)221128

mit den grundlegenden Anforderungen GSLA lt. Anhang I der Richtlinien über Medizinprodukte MDR 2017/745/EG übereinstimmt. Das Produkt wurde im Konformitäts-bewertungsverfahren nach Artikel 52, Absatz 7, Anhang II und III der MDR (EU) 2017/745 bewertet und nach Artikel 51, Anhang VIII der MDR in die untenstehende Klasse eingeordnet
complies with the general essential requirements according to Annex I of the MDR (EU) 2017/745 for medical products. The product was assessed by a conformity assessment procedure in accordance to Article 52, Section 7, Annex II and III of the MDR and classified in accordance to the MDR Article 51, Annex VIII into the class listed below

Klasse I / Class I

CE-Kennzeichnung
CE mark CE MD

Angewandte Normen, Richtlinien / Norms, Directives

EN 1041:2013-12	EN 15223-1:2016 (2020)
ISO 14971:2019	EN ISO 13485:2016
EN 62304:2015	MDR (EU) 2017/745

Gültig bis / valid until 18.10.2026

Benediktbeuern, 18.10.2023
MESA Medizintechnik GmbH

Günther Glatte
Geschäftsführer / General Manager