EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.:	HZ 1016120-1
Manufacturer:	**Comarch S.A.** Al. Jana Pawła II 39 A 31-864 Kraków Poland
EUDAMED Single Registration No.:	PL-MF-000010585
Products:	Class IIa devices: Z12030602 - VITAL SIGNS TELEMETRY RECEIVERS Z12030692 - VITAL SIGNS TELEMETRY INSTRUMENTS – MEDICAL DEVICE SOFTWARE Z12050401 - CARDIOVASCULAR HOLTER ANALYSERS Z12050492 - HOLTER SYSTEM INSTRUMENTS FOR CARDIOVASCULAR PARAMETERS - MEDICAL DEVICE SOFTWARE Z12050403 - ECG HOLTER RECORDERS Z1208010492 - CARDIOTOCOGRAPHIC TELEMETRY INSTRUMENTS - MEDICAL DEVICE SOFTWARE
Authorised representative(s):	Not applicable

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.:	84964626-20
Effective date:	2023-07-20
Expiry date:	2027-07-17
Issue date:	2023-07-20

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
BS-MDR-091

Jarosław Pyclik
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.: HZ 1016120-1

Manufacturer: **Comarch S.A.**
Aleja Jana Pawla II 39 A
31-864 Kraków
Poland

Certificate history		
Revision:	Description:	Issue date:
1	Initial revision	2022-07-18
2	Update related to validity date and expiry date	2023-05-16
3	Update related to scope extension and revised EMDN codes	2023-07-20

Report No.: 84964626-20

Effective date: 2023-07-20

Expiry date: 2027-07-17

Issue date: 2023-07-20

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

Jarosław Pyclik
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.