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 Pawla II 39 A 31-864 Kraków Poland
EUDAMED Single Registration No.:	PL-MF-000010585
Products:	Class IIa devices: - Z120504 - HOLTER SYSTEM INSTRUMENTS FOR CARDIOVASCULAR PARAMETERS - Z120801 - PRENATAL DIAGNOSIS INSTRUMENTS - Z120306 - VITAL SIGNS TELEMETRY INSTRUMENTS (ECG)
Authorised representative(s):	N/A

Certificate history		
Revision:	Description:	Issue date:
1	Initial revision	2022-07-18

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.:	84958333-70
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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

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