

EU Certificate

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

Registration No.: HZ 1016120-1

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

EUDAMED Single
Registration No.: PL-MF-000010585

Products: Products of class IIa:

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

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.

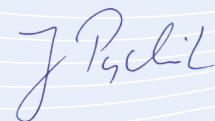
If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 84980136-20

Effective date: 2025-06-13

Expiry date: 2027-07-17

Issue date: 2025-06-13



Jarosław Pyclik

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

This certificate can be validated on <https://www.certipedia.com>

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

© TÜV, TÜEV and TÜV are registered trademarks. Utilisation and application requires prior approval.



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



TÜVRheinland®
Precisely Right.

EU Certificate

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

Registration No.: HZ 1016120-1
Manufacturer: Comarch S.A.
Aleja Jana Pawła II 39 A
31-864 Kraków
Poland

EUDAMED Single
Registration No.: PL-MF-000010585

Products of class IIb:

Z12030692 - VITAL SIGNS TELEMETRY INSTRUMENTS -
MEDICAL DEVICE SOFTWARE
INSTRUMENTS TO SUPPORT AND MONITOR
VITAL SIGNS

Authorized representative(s): Not applicable

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
4	Scope extension	2025-06-13

Report No.: 84980136-20
Effective date: 2025-06-13
Expiry date: 2027-07-17
Issue date: 2025-06-13



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

This certificate can be validated on <https://www.certipedia.com>

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



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



TÜVRheinland®
Precisely Right.