

Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 1016120-1

Organization: Comarch SA
al. Jana Pawła II 39a
31-864 Kraków
Poland

Scope: Design and development, own and contracted manufacturing, distribution and servicing of software, devices, accessories and systems for vital physiological functions monitoring as well as the post implementation services in the scope above.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 26300213 015

Effective date: 2020-09-08

Expiry date: 2022-02-21

Issue date: 2020-09-08



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No.	Facility	Scope
/01	Comarch SA al. Jana Pawła II 39a 31-864 Kraków Poland	Administration
/02	Comarch SA ul. Prof. Michała Życzkowskiego 27 31-864 Kraków Poland	Activity: Design and development, own and contracted manufacturing, distribution and servicing of software, devices, accessories and systems for vital physiological functions monitoring as well as the post implementation services in the scope above.
/03	Comarch SA ul. Stefana Jaracza 76/78 90-251 Łódź Poland	Activity: Design and development, own and contracted manufacturing, distribution and servicing of software, devices, accessories and systems for vital physiological functions monitoring as well as the post implementation services in the scope above.

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