

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
Comarch Healthcare S.A.
Al. Jana Pawla II 39 a
31-864 Krakow
Poland

has established and applies a quality management system for medical devices
for the following scope:

**Design and development, manufacture, distribution
and servicing of vital functions monitoring systems
as well as the post implementation services
(see attachment for sites included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-04-18
Certificate Registration No.: SX 60138393 0001
An audit was performed. Report No.: 26300158 014
This Certificate is valid until: 2021-01-08

Certification Body



Date 2019-04-18




Sebastian Mnizek

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60138393 0001
Report No.: 26300158 014

Organization: Comarch Healthcare S.A.
Al. Jana Pawla II 39 a
31-864 Krakow
Poland

Scope:

Sites included:

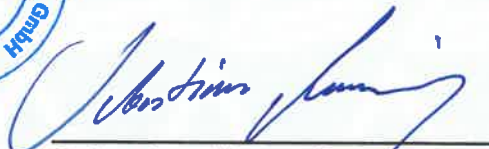
Comarch Healthcare S.A.
ul. Prof. Michala Zyczkowskiego 27
31-864 Krakow, Poland

Activity: Design and development, manufacture, distribution
and servicing of vital functions
monitoring systems

Comarch Healthcare S.A.
ul. Jaracza 76/78
90-251 Lodz, Poland

Activity: Design and development, manufacture of vital
functions monitoring systems as well as
post implementation services

Certification Body



Sebastian Mniszek

Date: 2019-04-18