

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60135088 0001

Report No.: 26300213 011

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

Products: (see attachments for products and sites included)

Replaces EC Certificate, Registration No.: HD 60112048 0001

Expiry Date: 2023-12-11

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2018-12-12

Date: 2018-12-11

Notified Body

Maciej Sciera

Maciej Sciera



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/2, Rev. 1

**Attachment to
Certificate**

Registration No.: HD 60135088 0001
Report No.: 26300213 012

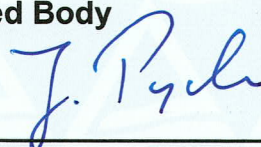
Manufacturer: Comarch S.A.
Aleja Jana Pawla II 39 A
31-864 Krakow
Poland

Products included:

- Patient data recorders, Long - Term, ECG
- ECG Patient monitor central station - software
- ECG viewing and analyzing software

Date: 2020-05-15

Notified Body



Jaroslaw Pyclik



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60135088 0001
Report No.: 26300213 011

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

Sites included:

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

Activity: Design/development

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

Activity: Design/development, production

Date: 2018-12-11

Notified Body


Maciej Sciera

