# EC Certificate

TÜVRheinland®

**Full Quality Assurance System**
**Directive 93/42/EEC on Medical Devices, Annex II excluding (4)**

Registration No.: HD 1032460-1

Manufacturer: ASPEL S.A.
os. H. Sienkiewicza 33
32-080 Zabierzów
Poland

Digitally signed by Morozov Maria
Date: 2022.06.17 16:27:18 EEST
Reason: MoldSign Signature
Location: Moldova

Products:
- Multichannel Electrocardiographs
- Ambulatory Electronic Automatic Sphygmomanometers, Long Term Recorders
- Ambulatory Electronic Automatic Sphygmomanometers, Long Term Analysing Software
- Spirometers
- Mouthpieces for Spirometer
- Pneumotachographs for Spirometer
- Ambulatory ECG, Long Term Recorders
- Ambulatory ECG, Long Term Analysing Software
- Data Management Systems, ECG
- Physiologic Monitoring Systems, Stress Exercise, Cardiac
- Physiologic Monitoring Systems, Stress Exercise, Cardiac, Software

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.

Report No.: 26300262 010

Effective date: 2021-05-24

Expiry date: 2024-05-26

Issue date: 2021-05-24

TÜV Rheinland LGA Products GmbH

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

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

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Manufacturer:
ASPEL S.A.
os. H. Sienkiewicza 33
32-080 Zabierzów
Poland

Products:
- Ergometers, Stress Exercise, Cardiac
- Treadmills, Stress Exercise, Cardiac
- Multichannel Electrocardiographs with Pulsoximetry Module
- Physiologic Monitoring Systems, Stress Exercise, Pulmonary, Ergospirometers

Replaces EC Certificate number HD 60144443 0001

Report No.: 26300262 010

Effective date: 2021-05-24

Expiry date: 2024-05-26

Issue date: 2021-05-24

TÜVRheinland LGA Products GmbH Zertifizierstelle

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