

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

Registration No.: HD 60099755 0001

Report No.: 26300262 001

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

Products: (see attachment for products included)

Replaces Approval, Registration No.: HD 60028801 0001

Expiry Date: 2020-02-08

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: 2015-02-12

Date: 2015-02-12

Notified Body



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. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60099755 0001
Report No.: 26300262 001

Manufacturer: ASPEL S.A.
os. H. Sienkiewicza 33
32-080 Zabierzów
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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
- Electroencephalographs
- Ambulatory ECG, Long Term Recorders
- Ambulatory ECG, Long Term Analysing Software
- Data Management Systems, ECG, Software
- Physiologic Monitoring Systems, Stress Exercise, Cardiac
- Ergometers, Stress Exercise, Cardiac
- Treadmills, Stress Exercise, Cardiac
- Software, Stress Exercise, Cardiac

Date: 2015-02-12

Notified Body



D. Swiatko



TÜVRheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle