EC Certificate

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

Registration No.: HD 60148180 0001

Report No.: 21220015 018

Manufacturer:

Fairpharm Vertriebs GmbH
Am Krebsenbach 5-7
83670 Bad Heilbrunn
Deutschland

Products: Description see attachment

Replaces Certificate, Registration No.: HD 60134411 0001

Expiry Date: 2024-05-26

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: 2020-03-25

Date: 2020-03-25

Notified Body

Roland Gruber

TÜV Rheinland LGA Products GmbH

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.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60148180 0001
Report No.: 21220015 018

Manufacturer: Fairpharm Vertriebs GmbH
Am Krebsenbach 5-7
83670 Bad Heilbrunn
Deutschland

Gastointestinal direct granules and powders for the treatment of digestive disorders

For the following devices the scope covers only the aspects of manufacture concerned with conformity of the products with the metrological requirements:
- measuring spoon with measuring function

Notified Body

Date: 2020-03-25

Roland Gruber

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle