

# EU Certificate

## Quality Management System REGULATION (EU) 2017/745 on Medical Devices Annex IX Chapter I, Section 2 and 3 and Chapter III


Registration No.: HZ 1144564-1  
Manufacturer: Fairpharm Vertriebs GmbH  
Am Krebsenbach 5-7  
83670 Bad Heilbrunn  
Germany  
EUDAMED Single Registration No.: DE-MF-000016959  
Products: Products of class IIb:  
G0401 - ORALLY ADMINISTERED DEVICES FOR THE  
THERAPY OF GASTRO-INTESTINAL DISORDERS  
Authorized representative(s): N/A

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-08-29

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.

If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 1116531-40  
Effective date: 2024-08-29  
Expiry date: 2029-08-28  
Issue date: 2024-08-29



Dipl.-Ing. A. Fechner  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on <https://www.certipedia.com>

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zflg.de  
BS-MDR-091

 **TÜVRheinland**<sup>®</sup>  
Precisely Right.