

# EU Quality Management System Certificate

mdc medical device certification GmbH

Kriegerstr. 6, 70191 Stuttgart, Germany  
Notified body (identification number 0483)

hereby certifies that the company (SRN: CH-MF-000026912)

ECO PHYSICS AG

Bubikonerstrasse 45  
8635 Dürnten  
Switzerland

EU Authorized Representative: ECO Physics GmbH, Gildenweg 6, 50354 Hürth, Germany

has implemented and applies a quality management system in accordance with Annex IX, Chapter I of Regulation (EU) 2017/745 for conformity assessment of the devices listed on the following pages.

An audit by mdc has proven that this quality management system fulfils the following requirements:

**Annex IX - Chapter I (Quality Management System)**

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate consists of 2 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from:	2022-11-09	Registration No.	D1053200020
Valid until:	2027-11-08	Evaluation Report No.	240241

Stuttgart, 2022-11-09

Head of Notified Body



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zflg.de](http://www.zflg.de)

BS-MDR-098

Devices:

Product: EXHALYZER D - Pulmonary Function Testing Device

Risk class: IIa

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