

EU DECLARATION OF CONFORMITY

(Regulation (EU) 2017/745 — Medical Device Regulation)

1. Manufacturer

Green Drain Europe ApS
Birk Centerpark 40
DK-7400 Herning
Denmark

Single Registration Number (SRN): DK-MF-000052289

2. Product Identification

Trade Name: Green Drain™
Device Type: Waterless Drain Trap Seal

Basic UDI-DI:
5745001471GreenDrainMDRJD

UDI-DI (Device Variants):

Variant	UDI-DI
GD125	5745001471002
GD15	5745001471019
GD2	5745001471026
GD3	5745001471033
GD35	5745001471040
GD4	5745001471057
GD5	5745001471064
GD6	5745001471071

3. Intended Purpose

Green Drain™ is a passive mechanical device intended for installation in floor drains. It functions as a one-way barrier allowing fluid passage while restricting the upward movement of air and aerosols from drainage systems.

The device is intended to support hygiene and infection prevention and control measures by reducing potential environmental exposure pathways.

The device does not have a direct medical, therapeutic, or diagnostic effect on the human body.

4. Risk Classification

The device is classified as:

Class I

in accordance with Annex VIII of MDR (EU) 2017/745.

5. Conformity Assessment Procedure

The conformity assessment procedure has been carried out in accordance with:

- Article 52(7) of MDR (EU) 2017/745

The manufacturer declares conformity under its sole responsibility.

6. Compliance with General Safety and Performance Requirements

The device complies with the applicable General Safety and Performance Requirements (GSPR) set out in Annex I of MDR (EU) 2017/745.

Compliance is demonstrated through:

- Annex II Technical Documentation
- GSPR Checklist
- Risk Management File (ISO 14971-aligned)
- Verification and Validation documentation

7. Standards and Common Specifications

The device has been evaluated against relevant standards and specifications, including:

- ASSE 1072 (Drain Trap Seal Devices)
- WMTS 522 (WaterMark Technical Specification)
- ETA-18/0536 (European Technical Assessment)

Additional quality system certifications supporting manufacturing include:

- ISO 9001:2015
- ISO 13485:2016

8. Additional Information

The device:

- is non-sterile
- has no measuring function
- contains no medicinal substances
- contains no software
- has no direct or indirect contact with the human body

9. Declaration

We hereby declare under our sole responsibility that the product described above is in conformity with the applicable provisions of MDR (EU) 2017/745.

10. Place and Date of Issue

Place: Herning

Date: 20 April 2026

11. Authorised Signatory

For and on behalf of the manufacturer:

Name: Keld Rindom

Function: Managing Director / PRRC

Signature: *Keld Rindom*

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