Green Drain™ — Regulatory Summary

Regulatory Classification

Green Drain™ is classified as a **Class I medical device** under Regulation (EU) 2017/745 (Medical Device Regulation, MDR).

The device is:

- non-sterile
- non-measuring
- non-invasive
- self-certified by the manufacturer

No Notified Body involvement is required.

Regulatory Position

Green Drain™ is a passive mechanical device intended for use in built environments, including healthcare settings.

The device does not act directly on the human body and has no therapeutic or diagnostic function. Its role is limited to environmental control within the scope of its intended purpose.

MDR applicability is based on the device's intended use as a supportive measure within infection prevention and control frameworks, specifically through the reduction of environmental exposure pathways associated with floor drain systems.

Conformity Assessment

Conformity has been established in accordance with:

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

The manufacturer declares conformity under its sole responsibility.

Compliance Framework

Compliance with MDR requirements is demonstrated through:

- Technical Documentation in accordance with Annex II
- General Safety and Performance Requirements (Annex I)
- Risk Management in alignment with ISO 14971 principles
- Verification and validation through laboratory and technical testing

A complete Technical Documentation file is maintained and made available to competent authorities upon request.

Device Identification

Green Drain™ is registered within the European database (EUDAMED).

- Manufacturer SRN: DK-MF-000052289
- Basic UDI-DI: 5745001471GreenDrainMDRJD

Device variants are uniquely identified through UDI-DI assignments.

Variant	UDI-DI
GD125	05745001471002
GD15	05745001471019
GD2	05745001471026
GD3	05745001471033
GD35	05745001471040
GD4	05745001471057
GD5	05745001471064
GD6	05745001471071

Manufacturing and Quality

The device is manufactured under established quality management systems, including:

- ISO 9001:2015
- ISO 13485:2016

Manufacturing processes include:

- batch-level traceability
- quality control and inspection procedures
- change control and corrective action processes

Scope and Limitations

Green Drain™ is a passive environmental control device.

- It does not prevent, diagnose, treat, or cure disease
- It does not provide patient-specific or clinical outcomes
- It does not replace established infection prevention measures

The device supports hygiene management by acting on environmental exposure pathways.

Its performance is based on controlled testing and must be understood within that context.

Public Documentation

The following documents are available:

- EU Declaration of Conformity
- Instructions for Use

Additional technical documentation is maintained by the manufacturer and can be provided to authorities where required.

End of Document