Green Drain™ — Technical Summary

Device Overview

Green Drain™ is a passive, non-powered mechanical device designed for installation in floor drains.
It functions as a one-way barrier that allows the passage of liquids while restricting the upward movement of air and aerosols from drainage systems.

The device contains no electronic components, no software, and does not interact directly with the human body.

Intended Purpose

Green Drain™ is intended for use in built environments, including healthcare settings, as a supportive measure within hygiene and infection prevention and control frameworks.

The device acts on environmental pathways by limiting the potential upward movement of air and aerosolised particles from drainage systems.

Green Drain™ does not have a direct medical, therapeutic, or diagnostic effect on humans.

Functional Principle

The device consists of a flexible elastomer membrane housed within a rigid structure.

- The membrane opens under downward pressure, allowing fluid drainage
- In the absence of flow, the membrane remains closed
- This creates a physical seal that restricts airflow from the drain

This passive mechanism operates without external energy and requires no user interaction once installed.

Key Characteristics

- Passive mechanical barrier (non-active device)
- Non-sterile, no measuring function
- No direct or indirect contact with the human body
- Designed for integration into standard drainage systems
- Available in multiple sizes (GD1.25–GD6)

Verification and Performance

The device has been evaluated using standardised laboratory and technical testing methods, including:

- Functional performance under controlled flow conditions
- Mechanical integrity and durability testing
- Dimensional conformity and manufacturing consistency
- Packaging and transport resilience

Laboratory testing using aerosol surrogate models has demonstrated a high level of containment under controlled conditions.

All performance data are derived from controlled testing environments and should be interpreted within that context.

Materials

The device is manufactured from:

- ABS polymer housing
- elastomer membrane (silicone-based)

No information indicating the presence of natural rubber latex is identified in the available material specifications.

Manufacturing and Quality

Production is carried out under established quality management systems, including:

- ISO 9001:2015
- ISO 13485:2016

Manufacturing includes:

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

Regulatory Status

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

The device complies with the applicable General Safety and Performance Requirements (Annex I).

A complete Technical Documentation file is maintained in accordance with Annex II.

The EU Declaration of Conformity is available upon request.

Important Information

Green Drain™ is a passive environmental control device.
It does not replace established hygiene protocols, cleaning procedures, or infection prevention measures.

Use of the device should be considered as one element within a broader hygiene management framework.

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