



TECHNICAL DATA SHEET MIFUSYMA001 - 09.10.2024 / MIFUSYMA001 - 23.07.2025

ENDORAIL SYSTEM

PRODUCT CODE: ESYSTEMGEN2V01

Manufacturing company	Endostart S.r.l. Via delle Regioni 265 50052 Certaldo (FI)
Device classification	Class I - non- sterile, Rule 1 and 13 according to MDR 2017/745, Annex VIII and Chapter III.
CND classification	G0399
Italian Health Minister Repertoire number registration	2274622
Lifetime	5 years

1. INTENDED USE

Endorail System is a medical device intended to facilitate endoscope positioning during endoscopy of the large and small intestine.

2. DEVICE DESCRIPTION

Endorail System is a reusable medical device which includes the following elements:

- Endorail Handpiece (EH),
- Endorail Cart (EC).

Endorail System must be used in combination with Endorail Set.

The Endorail handpiece contains a permanent magnet. It is used during endoscopy of small and large intestine, in which the user places the handpiece on the patient's abdomen in order to attract and lock in place the balloon catheter Endorail Balloon Guide (part of the medical device Endorail Set) filled with the ferromagnetic fluid.

Once the balloon guide is anchored, the positioning of the endoscope can be adjusted.

When not in use, the Endorail handpiece is stored in the Endorail Cart, which limits the exposure of the magnetic field generated by the magnet to objects and individuals.

The Endorail Cart is equipped with light and acoustic indicators whether the handpiece is in use or not and the magnet is properly stored.



Endorail Cart



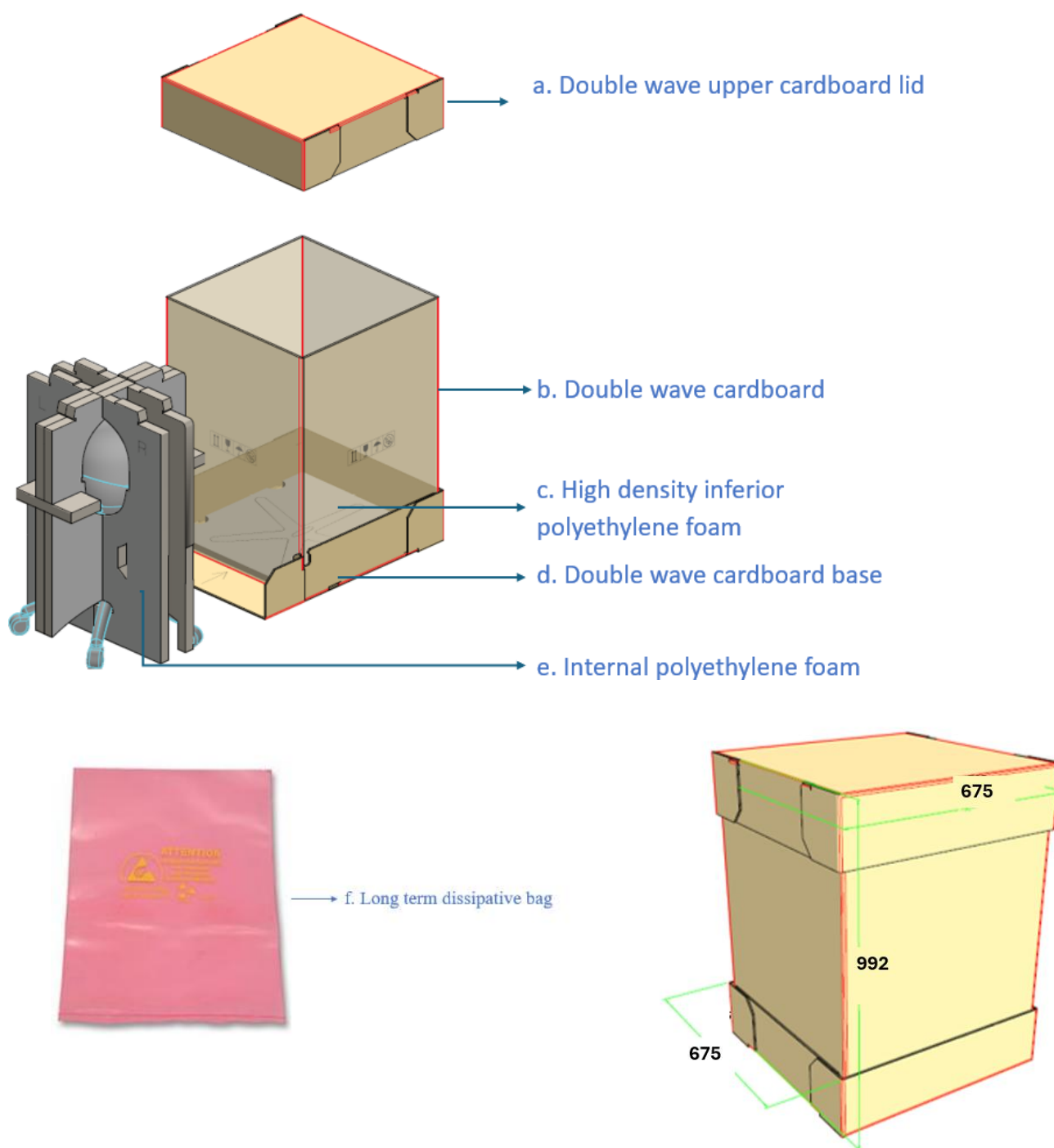
Endorail Handpiece

3. TECHNICAL FEATURES

	ENDORAIL HANDPIECE	ENDORAIL CART
Dimensions	Height: 242 mm Diameter: 116 mm	Height: 943 mm Width: 687 mm Depth: 721 mm
Weight	2,65 kg	18 kg
Power supply	-	2 non-rechargeable batteries C (LR14) PC1400 Rated voltage 1.5 V
Materials	Polyamide	Polyamide
Coating	White base food safe: GRAPHITE HD	White base food safe: GRAPHITE HD
Main Components	Permanent magnet: MPN 52 (NdFeB) – Sintered – Anisotropic; dimensions: $\phi=86\text{mm}$, $h=45\text{mm}$	Electronic board.
Storage conditions	The device shall be stored in a cool and dry place	The device shall be stored in a cool and dry place

ELECTRONIC BOARD - SOFTWARE	
Function	<p>The software aims to recognize the magnet position and its status (in use, properly stored, not properly stored) through visual and acoustic indications.</p> <p>It is not intended to provide information used to take decisions with diagnostic or therapeutic purposes (see Instructions for use manual).</p>

4. PACKAGING



5. REGULATORY REQUIREMENTS

Biocompatibility	Device complies with: <ul style="list-style-type: none"> - CEI EN 10993-1 “Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process”
Electrical safety compatibility	Device complies with standard: <ul style="list-style-type: none"> - CEI EN 60601-1 “Medical electrical equipment - Part 1: General requirements for basic safety and essential performance”
Electromagnetic compatibility	Device complies with collateral standard: <ul style="list-style-type: none"> - CEI EN 60601-1-2 “Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests”
Software	Device complies with: <ul style="list-style-type: none"> - CEI EN 62304 “Medical device software — Software life cycle processes”
Usability	Device complies with: <ul style="list-style-type: none"> - CEI EN 62366-1 “Medical devices Application of usability engineering to medical devices” - CEI EN 60601-1-6 “Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability”
Packaging	Device complies with: <ul style="list-style-type: none"> - ASTM D4169 “Standard Practice for Performance Testing of Shipping Containers and Systems” - ASTM F1886/F1886M “Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection” - ASTM D4332 “Standard Practice for Conditioning Containers, Packages, Or Packaging Components for Testing”