

## EU Declaration of Conformity

I declare on behalf of Endocarts International Limited that the following group of products fulfill the general safety and performance requirements of Medical Device Regulations 2017/745 based on conformity assessment in Annexes II and III.

**Product Group Name:** Endoscopy Cart  
**Classification:** Class I of Rule 1  
**Basic UDI-DI:** 506067173ENDC000001RM



**Manufacturer:** Endocarts International Ltd

55 Vanguard Way, Shoeburyness, Essex,  
 SS3 9QY, United Kingdom

**Single Registration Number (SRN):** GB-MF-000004309



**Authorized Representative:** Acorn Regulatory Consultancy Services

Knockmorris, Cahir, Co. Tipperary,  
 E21R766, Ireland

**Single Registration Number (SRN):** IE-AR-000000592

Are in conformity with the following standards:

Reference	Title
BS EN 60601-1:2006	Medical electrical equipment. General requirements for basic safety and essential performance ( <i>only with respect to instability requirements</i> )
BS EN 60601-1-2:2015	Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests <i>(only with respect to product with isolation transformer)</i>
BS EN ISO 14971:2019	Medical devices — Application of risk management to medical devices
BS EN ISO 62366-1:2015	Medical devices — Application of usability engineering to medical devices
BS EN ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
BS EN ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1 General requirements

This declaration of conformity has been issued under the sole responsibility of Endocarts International Limited for the compliance of the products listed below.

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Name: Renato Pichierri  
Function: Director  
Place of Issue: 55 Vanguard Way,  
Shoeburyness, Essex, SS3  
9QY, United Kingdom  
Date of Issue: 12/12/2024  
Issue No: DoC001 v9

Model/Trade Name	Part Number	UDI-DI (GTIN-14)
VC-2010	103320	05060671730007
VC-2010	103321	05060671730014
VC-2010MX	103343	05060671730038
VC-2010MX	103344	05060671730045
VC-2010MX	103345	05060671730052
VC-2010MC	103330	05060671730021
VC-2010FMS	102143	05060671730168
VC-2010FMS	102141	05060671730458
VC-2010ENT	104565	05060671730267
VC-2020 With transformer	102180	05060671730847
VC-2020	102181	05060671730854
VC-480	101243	05060671730366
VC-480	101247	05060671730199
VC-480	101248	05060671730205
VC-480	101260	05060671730212
VC-480	101261	05060671730229
VC-480	101285	05060671730090
VC-480	101286	05060671730106
VC-480	101295	05060671730489
VC-480	101296	05060671730472
VC-480	101299	05060671730496
VC-480	101300	05060671730175
VC-480	101420	05060671730427
VC-480	101421	05060671730434
VIDEO CART	102140	05060671730120
ST-5	104054	05060671730236
E-Trans 6	104710	05060671730328
Endotrans	104476	05060671730342
MIG-20 LITE	104711	05060671730519
MIG-10 LITE	104715	05060671730502
MIG-20	104490	05060671730694
MIG-20	104491	05060671730698
S/N-2 Lens	101310	05060671730533
SN-2 LENS	101315	05060671730113
OPF-1	106160	05060671730137
EC-3	100932	05060671730410
AES-1	103418	05060671730069
AES-5	102230	05060671730281
AES1 Cart with transformer	103423	05060671730830
VC-2010 ENT with 2KvA Isolation Transformer	104564	05060671730731

VC-2010HF	102175	05060671730649
FF-4 Cart	104530GR	05060671730687
FF-4 Cart with Transformer	104531GR	05060671730274
FF-5 Cart with Transformer	104428	05060671730816
AES-2 Caiman Cart	103402	05060671730243
32" Monitor Cart	100931	05060671730441
MIG-10 Cart with Transformer	104560	05060671730588
MIG-10 Cart	104561	05060671730595
MIG-20 Cart with Transformer	103439	05060671730632
MIG-20 Cart	104496	05060671730786
MIG-20 Cart with Transformer	104497	05060671730793
EC-55 Monitor Cart	100450	05060671730557
Endotrans cart with 6 Trays	103630EC	05060671730700
Endotrans 6 tray cart (no tray)	103626EC	05060671730670
Endotrans cart with 10 trays	103631EC	05060671730748
Endotrans 10 tray cart (no tray)	103627EC	05060671730755
Endotrans Wide cart with 10 trays	103632EC	05060671730762
Endotrans Wide 10 tray cart (no tray)	103628EC	05060671730779
Procedure Cart	103790	05060671730809
Richard Wolf Morcellator Cart	100460	05060671730861

### Intended purpose of the device

To safely accommodate and transport the medical equipment it carries.