Declaration of Conformity

Declaration of conformity n° **DC035**
Revision n° **Rev.11**
Technical file # **10**

Legal manufacturer	Medline International France SAS 5 rue Charles Lindberg 44110 Châteaubriant, France	
	Single Registration Number	Not yet available
EU representative	N/A	
	Single Registration Number	Not yet available
Product range	Flexible Enema administration unit	
Product codes	DYNDE70100	
Classification	Class I non-sterile, Rule 5	
GMDN codes	35050 Gravity Enema Set	

European Union Regulations:

We herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the following EU Regulations and/or Council Directive(s) as transposed into national laws.

Applicable directive:	Medical Device Regulation (EU) 2017/745
Conformity assessment procedure per MDR 2017/745	II and III
Notified Body	N/A
Certificate n°	N/A
First Issued (Place/Date)	N/A
Applicable standards and/or Common Specifications	Listed in technical file # 10

Australian Regulations:

This is a declaration of conformity made under clause 6.6 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.
Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles and the classification rules before being supplied.

All supporting documentation is retained at the premises of the manufacturer.

Authorised Signatory:

Kenneth Smith Digitally signed by Kenneth Smith Date: 2020.07.02 15:54:39 +02'00'

Kenneth Smith	44110 Châteaubriant - France	July 2nd 2020
Senior QA/RA Manager	*Place*	*Date*

List of finished products for declaration of conformity

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Catalog number	GMDN code	Product description	MD Class	PPE Category	Basic UDI-DI:
DYNDE70100	35050	Flexible enema administration set	I NS		00888277603786

GMDN Code only for products classified as Medical devices.	
35050	Bag, enema