

EU Declaration of Conformity according to Medical Device Regulation (EU) 2017/745

Manufacturer name: Cedic s.r.l.

Manufacturer registered place of

business:

Via Liberazione, 63/9 - 20068 Peschiera Borromeo (MI) - Italy

SRN: Not yet issued

Products: Please refer to the below list

Risk Class: Class I

Conformity assessment procedure: MDR EU 2017/745, Article 52, paraghaph 7 (first sentence)

Common Specifications: N/A
Notified Body: N/A

NB Identification Number: N/A

Certificate N°: N/A
Certificate Validity: N/A

DoC Validity: 3 years – 26 May 2024

I declare under our sole responsibility that the medical device/s covered by the present declaration meet the provisions of the Medical Device Regulation EU 2017/745 and that we are solely responsible for issuing this EU Declaration of Conformity.

Place & date of issue: Peschiera Borromeo, 26th May 2021

Position Name Signature Date

Global Quality System &

Regulatory Affairs Manager -

PRRC

Giulia Spagnolini

26/05/2021

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Products List

Product Code	Product Ref.	Product Name	Basic UDI-DI
F00070	7149 00	Enteral Distal End ENFit Transition Connector	805609372TD00182
F00092	589828	Transition step Connector to Funnel tube	
F00093	589732	Transition connector to ENLock/Funnel tube	
F00094	589733	Transition Connector to reversed Luer Medport	
F00095	589734	Transition Connector for ENLock set / ENLock syringe	
F00098	589738	Transition Connector to Oral/Luer Syringe	
F00104	F00104	Transition connector to ENLock/Funnel tube	
F00106	F00106	Enteral Funnel ENFit Transition Connector	
		with cap	
F00110	12298016	Compat Adapter Enfit Set → US Funnel Tube	
F00116	777444	Enteral Distal End ENFit Transition Connector	
F00123	G 44989	Enteral Distal End ENFit Transition Connector	
F00125	F00125	ENFit to Reverse Luer Transition Connector	
		with cap	
F00127	F00127	Luer to ENFit Transition Connector with cap	
F00133	F00133	Enteral Distal End ENFit Transition Connector	
F00135	12319560	Compat Adapter Stepped Set → ENFit Tube	
F00148	F00148	Oral/Luer Enteral Transition Connector for	
		Medication Port	
F00151	12334450	Compat adapter ENFit transition kit	
F00168	613734	ENFit Funnel Adapter	

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