



Campfield Road
Shoeburyness
SS3 9BX

EU- Declaration of Conformity

issued under the sole responsibility of the manufacturer listed below:

Manufacturer's Name	Cantel (UK) Ltd
Manufacturer's address/ SRN	Campfield Road, Shoeburyness, SS3 9BX. UK
EU Representative Address/ SRN	Cantel Medical (Italy) S.r.l. a socio unico Via Laurentina, 169 00071 Pomezia (RM) – Italia
Quality System Cert No.	LRQ00001040/B
Notified Body No./Name	LRQA
CE Certificate No.	N/A

As the manufacturer listed above, we declare that the devices listed:

Product(s):	UNO-FLUSH™ 200ml with Scope Shaped Sponge UNO-FLUSH™ 300ml with Scope Shaped Sponge UNO-FLUSH™ 500ml with Scope Shaped Sponge UNO-WIPE™ Sponge
REF:	105008, 105005, 105006, 105009
Basic UDI-DI:	506018978TDF-00025LS
Intended Purpose:	UNO-FLUSH™ is a convenient, space saving, pre-cleaning kit containing a low foaming cleanser intended for the post procedural, initial flush and wipe of an endoscope at the bedside. UNO-WIPE™ Sponge is a convenient, space saving, pre-cleaning kit impregnated with UNO-FLUSH™ intended for the post procedural, initial wipe of a non-lumen endoscope, at the bedside.
Applied standards:	EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021, EN ISO 15223-1:2016, EN 62366-1:2015+A1:2020

Meets all conformity requirements of the safety and performance requirements of the Medical Devices Regulation (MDR, Regulation (EU) 2017/745 as amended).

Product classification according to the requirements described in Annex VIII of the Medical Devices Regulation, the medical device is assigned to risk class I (conformity assessment per Annex IX).

Name: **Richard Manford**

Signature:

DocuSigned by:

8E1EFA113D314CA...

Title:

Director Regulatory Affairs, EMEA

Place of Issue: **Shoeburyness, UK**

Date of Issue: **23 May 2021**