

DECLARATION OF CONFORMITY

Manufacturer: US Endoscopy, 5976 Heisley Road, Mentor, OH, USA, 44060

Authorized Representative: STERIS Ireland Limited, IDA Business and Technology Park, Tullamore, County Offaly R35 X865, Ireland

EU-27 Notified Body

(currently the responsible notified body):

British Standards Institution
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands
Notified Body Number 2797

UK Notified Body

(previous responsible notified body):

British Standards Institution
Davy Avenue
Milton Keynes
Buckinghamshire MK5 8PP
United Kingdom
Notified Body Number 0086

CE Certificate: 02112

We declare, under our sole responsibility, that the following sterile and non-active devices for endoscopy to which this declaration relates are in conformity with the Medical Device Directive, 93/42/EEC 1993, M5, Annex V section 3.2. All supporting documentation is on file at the address of the manufacturer shown above.

P/N	NAME	CLASS	RULE
711094	EXACTO COLD SNARE 20/BOX	I	5
711095	EXACTO COLD SNARE 50/BOX	I	5
711115	EXACTO® COLD SNARE	I	5
711141	FALCON® ROTATABLE RETRIEVAL BASKET (STERILE)	I	5
711162	ROTH NET®FOREIGN BODY-STANDARD, STERILE	I	5
711165	ROTH NET®FOREIGN BODY-MAXI, STERILE	I	5
711168	ROTH NET®FOREIGN BODY-MINI, STERILE	I	5
711169	ROTH NET® SELECT	1	5
711175	TALON ® GRASPING DEVICE (STERILE)	I	5
711177	RAPTOR® GRASPING DEVICE	I	5
711178	RAPTOR® GRASPING DEVICE - MINI	I	5
711198	ROTH NET RETRIEVER – SELECT 360	I	5
715060	ROTH NET®PLATINUM®-UNIVERSAL, STERILE	I	5
715160	ROTH NET®PLATINUM®-POLYP, STERILE	I	5
711128	BIOSHIELD® BIOPSY VALVE, STERILE	I	2
711159	ROTH NET®RETRIEVER-MINI POLYP	I	5
711201	BIOPSY FORCEPS, (2.3 MM), (230 CM)	I	5
711202	BIOPSY FORCEPS, (2.3 MM), (230 CM)	I	5
711203	BIOPSY FORCEPS, (2.3 MM), (160 CM)	I	5
711204	BIOPSY FORCEPS, (2.3 MM), (160 CM)	I	5
711205	BIOPSY FORCEPS-SHEATHED, (2.3 MM), (230 CM)	I	5
711261	BIOPSY FORCEPS-PEDIATRIC, (1.75 MM), (160 CM)	I	5
711660	HISTOGUIDE WIRE GUIDED FORCEPS	I	5
711262	BIOPSY FORCEPS-PEDIATRIC, (1.75 MM), (160 CM)	I	5
711291	BIOPSY FORCEPS-ENTEROSCOPE, (2.3 MM), (350 CM)	I	5
711499	INFINITY® CYTOLOGY BRUSH	I	5
711623	ProArmor endoscope tip protector	1	1
711652	INFINITY® SAMPLING DEVICE	I	5
711653	INFINITY® ERCP SAMPLING DEVICE	I	5
711891	ORACLE® EUS BALLOON	I	5
711892	ORACLE® EUS BALLOON, Olympus Radial	I	5
711893	ORACLE® EUS BALLOON, Olympus Linear	I	5

Name:	Jennifer Nalepka	Title:	Lead Regulatory Affairs Specialist
Signature:	<i>Jennifer Nalepka</i>	Date:	3-12-2020