

3/2024

Declaration of conformity

ENDOMED S.R.L., with its seat in Italy, Via Ugo La Malfa snc 04020, Spigno Saturnia (LT), declares under its own responsibility, that the following medical devices called:

Rigid Endoscopes

Device	Description	UDI-DI DI BASE
Cystoscope	Rigid endoscope for cystoscopy surgery. High definition, grandangled, autoclavable (max 134°C/2,3 bar/5 min).	805257066CISTOC8
Arthroscope	Rigid endoscope for arthroscopy surgery. High definition, grandangled, autoclavable (max 134°C/2,3 bar/5 min).	805257066ARTRODG
Laparoscope	Rigid endoscope for laparoscopy surgery. High definition, grandangled, autoclavable (max 134°C/2,3 bar/5 min).	805257066LAPAROCY
Hysteroscope	Rigid endoscope for hysteroscopy surgery. High definition, grandangled, autoclavable (max 134°C/2,3 bar/5 min).	805257066ISTEROKF
Endoscope for Urethroscopy and ureterorenoscopy	Rigid endoscope for Urethroscopy and ureterorenoscopy surgery. High definition, grandangled, autoclavable (max 134°C/2,3 bar/5 min).	805257066URETEROXL
Nephroscope	Rigid endoscope for nephroscopy surgery. High definition, grandangled, autoclavable (max 134°C/2,3 bar/5 min).	805257066NEFROCW

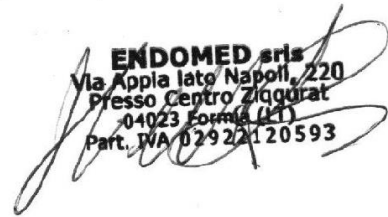
Risk class IIa, as per rule nr. 7 of annex IX of Directive 93/42 / ECC (received in Italy with Legislative Decree of 24 of February 1997, n. 46), modified from Directive 2007/47/CE (received in Italy with Legislative Decree of 25 of January 2010, nr. 37):

- Comply to essential requirements and to rules of ECC/93/42 Directive, as per technical file FT007EM;
- are manufactured according to the Quality System that meets the requirements of Annex V of the above mentioned legislative decree, as per Certification nr. IT280020-4 released on 13th of May 2021 from BUREAU VERITAS ITALIA S.p.a. Notified Body n. 1370, Viale Monza, n. 347 - 20126 MILANO.
- Devices comply UE Regulation 2017/745 relevant to applicable requirements of legacy device of art. 120(3). Devices comply also to UE Regulation (UE) 2023/607 that

modifies Regulation (UE) 2017/745 for what concerns transitional provisions for some medical devices.

Spigno Saturnia (LT), 08/07/2024

CEO
 (Michele Lionetti)



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 Presso Centro Ziqurat
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 Part. IVA 02922120593

ANNEX 06_FT007 EM

CODE	DESCRIPTION	CLASS
40302LA.HD	Medici Hysteroscope, HD - autoclavable Ø 2,9 mm, 0°, WL 302 mm	IIA
40302LB.HD	Medici Hysteroscope HD- autoclavable - Ø 2,9 mm 12°, WL302 mm	IIA
40302LE.HD	Medici Hysteroscope HD- autoclavable - Ø 2,9 mm 30°, WL302 mm	IIA
40302LG.HD	Medici Hysteroscope, HD - autoclavable Ø 2,9 mm, 70°, WL 302 mm	
40302NA.HD	Medici Hysteroscope, HD - autoclavable Ø 4,0 mm, 0°, WL 302 mm	IIA
40302NB.HD	Medici Hysteroscope, HD - autoclavable Ø 4,0 mm, 12°, WL 302 mm	IIA
40302ND.HD	Medici Hysteroscope, HD - autoclavable Ø 4,0 mm, 25°, WL 302 mm	IIA
40302NE.HD	Medici Hysteroscope, HD - autoclavable Ø 4,0 mm, 30°, WL 302 mm	IIA
40302NG.HD	Medici Hysteroscope, HD - autoclavable Ø 4,0 mm, 70°, WL 302 mm	IIA
40260CA.HD	Medici Hysteroscope, HD - autoclavable Ø 2,0 mm, 0°, WL 260 mm	IIA
40260CE.HD	Medici Hysteroscope, HD - autoclavable Ø 2,0 mm, 30°, WL 260 mm	IIA
10200PA.HD	Medici Laparoscope, HD, Autoclavable, Ø5,0 mm, DOV 0°, WL 200 mm	IIA
10300PA.HD	Medici Laparoscope, HD, Autoclavable, Ø5,0 mm, DOV 0°, WL 300 mm	IIA

10300PE.HD	Medici Laparoscope, HD, Autoclavable, Ø5,0 mm, DOV 30°, WL 300 mm	IIA
10332PA.HD	Medici Laparoscope, HD, Autoclavable, Ø5,0 mm, DOV 0°, WL 332 mm	IIA
10332PE.HD	Medici Laparoscope, HD, Autoclavable, Ø5,0 mm, DOV 30°, WL 332 mm	IIA
10314UA.HD	Medici Laparoscope, HD, Autoclavable, Ø10,0 mm, DOV 0°, WL 314 mm	IIA
10314UE.HD	Medici Laparoscope, HD, Autoclavable, Ø10,0 mm, DOV 30°, WL 314 mm	IIA
10314UF.HD	Medici Laparoscope, HD, Autoclavable, Ø10,0 mm, DOV 45°, WL 314 mm	IIA
10310UA.4K	Medici Laparoscope, HD, Autoclavable, Ø10,0 mm, DOV 0°, WL 310 mm	IIA
10314UE.4K	Medici Laparoscope, HD, Autoclavable, Ø10,0 mm, DOV 30°, WL 310 mm	IIA
10350SA.HD	Medici Laparoscope, HD, Autoclavable, Ø6,5 mm, DOV 0°, WL 350 mm	IIA
10350SE.HD	Medici Laparoscope, HD, Autoclavable, Ø6,5 mm, DOV 30°, WL 350 mm	IIA
10130TA.HD	Medici Laparoscope, HD, Autoclavable, Ø8,0 mm, DOV 0°, WL 130 mm	IIA
10340TA.HD	Medici Laparoscope, HD, Autoclavable, Ø8,0 mm, DOV 0°, WL 340 mm	IIA
10340TD.HD	Medici Laparoscope, HD, Autoclavable, Ø8,0 mm, DOV 30°, WL 340 mm	IIA
10300UA.HD	Medici Laparoscope, HD, Autoclavable, Ø10,0 mm, DOV 0°, WL 320 mm	IIA
10320UE.HD	Medici Laparoscope, HD, Autoclavable, Ø10,0 mm, DOV 30°, WL 320 mm	IIA
10320UF.HD	Medici Laparoscope, HD, Autoclavable, Ø10,0 mm, DOV 45°, WL 320 mm	IIA
10340UA.HD	Medici Laparoscope, HD, Autoclavable, Ø10,0 mm, DOV 0°, WL 340 mm	IIA
10340UE.HD	Medici Laparoscope, HD, Autoclavable, Ø10,0 mm, DOV 30°, WL 340 mm	IIA
30069BA.HD	Medici Arthroscope, HD, Autoclavable, Ø1,9 mm, DOV 0°, WL 69 mm	IIA
30069BE.HD	Medici Arthroscope, HD, Autoclavable, Ø1,9 mm, DOV 30°, WL 69 mm	IIA
30102BA.HD	Medici Arthroscope, HD, Autoclavable, Ø1,9 mm, DOV 0°, WL 102 mm	IIA
30102BE.HD	Medici Arthroscope, HD, Autoclavable, Ø1,9 mm, DOV 30°, WL 102 mm	IIA
30188LA.HD	Medici Arthroscope, HD, Autoclavable, Ø2,9 mm, DOV 0°, WL 188 mm	IIA
30188LE.HD	Medici Arthroscope, HD, Autoclavable, Ø2,9 mm, DOV 30°, WL 188 mm	IIA
30188LG.HD	Medici Arthroscope, HD, Autoclavable, Ø2,9 mm, DOV 70°, WL 188 mm	IIA
30175LA.HD	Medici Arthroscope, HD, Autoclavable, Ø2,9 mm, DOV 0°, WL 175 mm	IIA
30175LE.HD	Medici Arthroscope, HD, Autoclavable, Ø2,9 mm, DOV 30°, WL 175 mm	IIA

30175LG.HD	Medici Arthroscope, HD, Autoclavable, Ø2,9 mm, DOV 70°, WL 175 mm	IIA
30110LA.HD	Medici Arthroscope, HD, Autoclavable, Ø2,9 mm, DOV 0°, WL 110 mm	IIA
30110LE.HD	Medici Arthroscope, HD, Autoclavable, Ø2,9 mm, DOV 30°, WL 110 mm	IIA
30110LG.HD	Medici Arthroscope, HD, Autoclavable, Ø2,9 mm, DOV 70°, WL 110 mm	IIA
30188NA.HD	Medici Arthroscope, HD, Autoclavable, Ø4,0 mm, DOV 0°, WL 188 mm	IIA
30188NE.HD	Medici Arthroscope, HD, Autoclavable, Ø4,0 mm, DOV 30°, WL 188 mm	IIA
30188NF.HD	Medici Arthroscope, HD, Autoclavable, Ø4,0 mm, DOV 45°, WL 188 mm	IIA
30188NG.HD	Medici Arthroscope, HD, Autoclavable, Ø4,0 mm, DOV 70°, WL 188 mm	IIA
30175NA.HD	Medici Arthroscope, HD, Autoclavable, Ø4,0 mm, DOV 0°, WL 175 mm	IIA
30175NE.HD	Medici Arthroscope, HD, Autoclavable, Ø4,0 mm, DOV 30°, WL 175 mm	IIA
30175NF.HD	Medici Arthroscope, HD, Autoclavable, Ø4,0 mm, DOV 45°, WL 175 mm	IIA
30175NG.HD	Medici Arthroscope, HD, Autoclavable, Ø4,0 mm, DOV 70°, WL 175 mm	IIA
30142NA.HD	Medici Arthroscope, HD, Autoclavable, Ø4,0 mm, DOV 0°, WL 142 mm	IIA
30142NE.HD	Medici Arthroscope, HD, Autoclavable, Ø4,0 mm, DOV 30°, WL 142 mm	IIA
30142NF.HD	Medici Arthroscope, HD, Autoclavable, Ø4,0 mm, DOV 45°, WL 142 mm	IIA
30142NG.HD	Medici Arthroscope, HD, Autoclavable, Ø4,0 mm, DOV 70°, WL 142 mm	IIA
30110NA.HD	Medici Arthroscope, HD, Autoclavable, Ø4,0 mm, DOV 0°, WL 110 mm	IIA
30110NE.HD	Medici Arthroscope, HD, Autoclavable, Ø4,0 mm, DOV 30°, WL 110 mm	IIA
30110NF.HD	Medici Arthroscope, HD, Autoclavable, Ø4,0 mm, DOV 45°, WL 110 mm	IIA
30110NG.HD	Medici Arthroscope, HD, Autoclavable, Ø4,0 mm, DOV 70°, WL 110 mm	IIA
30188GA.HD	Medici Arthroscope, HD, Autoclavable, Ø2,7 mm, DOV 0°, WL 188 mm	IIA
30188GE.HD	Medici Arthroscope, HD, Autoclavable, Ø2,7 mm, DOV 30°, WL 188 mm	IIA
30188GG.HD	Medici Arthroscope, HD, Autoclavable, Ø2,7 mm, DOV 70°, WL 188 mm	IIA
30175GA.HD	Medici Arthroscope, HD, Autoclavable, Ø2,7 mm, DOV 0°, WL 175 mm	IIA
30175GE.HD	Medici Arthroscope, HD, Autoclavable, Ø2,7 mm, DOV 30°, WL 175 mm	IIA
30175GG.HD	Medici Arthroscope, HD, Autoclavable, Ø2,7 mm, DOV 70°, WL 175 mm	IIA
30110GA.HD	Medici Arthroscope, HD, Autoclavable, Ø2,7 mm, DOV 0°, WL 110 mm	IIA

30110GE.HD	Medici Arthroscope, HD, Autoclavable, Ø2,7 mm, DOV 30°, WL 110 mm	IIA
30110GG.HD	Medici Arthroscope, HD, Autoclavable, Ø2,7 mm, DOV 70°, WL 110 mm	IIA

Spigno Saturnia (LT), 08/07/2024

Il legale Rappresentante
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