



91 'E I 5@HMA 5B5; 9A 9BHGMGHA '7 9FH: 7 5I9'

Certificate no. 116/MDR

On the basis of the assessment carried out according to the Annex IX chapters I and III of the Regulation (EU) 2017/745, we hereby certify that the full quality management system established, documented and implemented:

by the Manufacturer: 7 5BH9@A 98-7 5@fH5@M'GF@  
00071 PO MEZIA (RM) - VIA LA URENTINA 169 (ITA) - Italy  
SRN: IT-MF-000007606

for the following devices

7 c'X'W'Ya ]WU'k Ug\Yf'gHf]nYf'ZcfYbXcgMcdYg  
7 c'X'W'Ya ]WU'k Ug\Yf'X]g]bZYWcf'ZcfYbXcgMcdYg  
K Ug\Yf'X]g]bZYWcf'dUgg]h'fci [ \ 'ZcfZYI ]V'Y'YbXcgMcdYg

complies and ensures the compliance of such devices with the applicable requirements of the aforementioned EU Regulation and it is subject to surveillance as required by the same Annex, section 3.

Further details are indicated in the Technical Attachment which is integral and substantial part of this certificate.

H ]g'91 '7 Yfh]WUHY ]g]ggj YX'Vm-A E 'G'd"5""Ug'Bch]ZYX'6cXmbc""\$\$)%Zcf'HY'FY[ i 'U]h'cb'f]l E'&\$%+##+() 'fY'UH'X'hc'a YX]WU'XYj ]W'g'

Examinations and tests performed (references to applied common specifications and/or standard included) are documented in the relevant IMQ's conformity assessment Report, traceable through the IMQ's Project (indicated in the section "Revision history" below) and available on request.

First issue date: 2023-07-31

Expiry Date: 2028-07-30

A E



# 5`Y[ Uhc`HYWb]Mc`U`7 Yfh]Z]WUhc`I`9`b"%%\* #A 8F

Technical Attachment of EU Certificate no. 116/MDR

## GMXYXU`HYWb]WU`b" & Technical sheet no. 2

7 UHY [ cfU`X]X]gdcg]hj] c.	@j U`X]g]bZ]HUF]W`W]a ]WU`U`ZYXXc`dYfYbXcgWcd]
Device category:	Cold chemical washer/disinfector for endoscopes
8Yg]hbUn]cbY`X]i]gc.	8]gdcg]hj] c`a`YX]Mc`XYg]hbUhc`U`Uj U[ [ ]c`X]g]bZ]n]cbY`W]a ]WU`U`ZYXXc`X]`YbXcgWcd] f[ ]X]`Y`ZYgg]V]]
Intended purpose:	Medical device intended for washing and cold chemical disinfection of rigid and flexible endoscopes
7`UggY`X]`f]gW]c.	=V
Risk class	IIB
G]hc`#]`XY`:`UVVf]WU`bHY`#	!`\$\$\$+%DC A`9N5`fFA`E!`J`5`@5I`F9BHB5`%*`f#5E!`!`#U`m
Manufacturer's site(s):	
F]Z]f]a`Yb]h]`UX`U`f]`W`fh]Z]WU]h]` bY`W`ggU]f]`dY`f`f]a`a`]gg]cbY`g]` a`Y`f`W`U`c`X]`X]`gdcg]hj]`]]`b` ei`Y`g]h]cbY.	Bcb`Udd`]WUV]Y
Reference to other certificates required for the placing on the market of the covered devices	Not applicable
7`cbX]n]cb]c`]]`a`]hUn]cb]X]` j`U`X]f].	BYgg]`bU
Conditions for or limitations to the validity:	None
5`fY`]bZ]fa`Un]cb]`f]Y]`Ub]h].	BYgg]`bU
Other relevant data:	None
8U]h]XY]X]gdcg]hj].	=XU]h]XY]X]gdcg]hj]`]`gc`bc`Y`Y`b`W`U]h]`bY`X`c`W`a`Y`b`h`c`f`Y`b`W`c`X]`X]`gdcg]hj]`]]`c`[ ]`Y`h`c`X]`Y`7`Y`fh]Z]WUhc`I`9`b"%%* #A 8F`f]f]Y]`]]`%`XY`]]`&\$&'`#`\$`+`#`%`U`Y`[`U`h`c`U`d`f`Y`g`y`b`h`Y`W`f`h]Z]WUhc`]]`H`U`Y`X`c`W`a`Y`b`h`c`W`c`g]h]i`]g]W`d`U`f`Y`]]`b`h`Y`[`f`U`b`h`Y`Y`g`c`g]h]b]n]U`Y`X]`Y`d`f`Y`g`y`b`h`Y`W`f`h]Z]WUhc`]]`
Device data:	Data of the devices are listed in the document



5`Y[ Uhc 'HYWb]Mc 'U`7 Yfh]Z]WUhc 'I 9'b"%%\* #A 8F

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Ghc f]Mc 'XY`Y 'fyj ]g]cb]'

Revision history

B" No.	8UW Date	F]Z]f]a Ybhc 'DfU]WU`A E` Reference to IMQ Project	8YgW]h]cbY Description
1	2023-07-31	DM22-0082169-01	Df]a U`Ya ]gg]cbY First Issue








