

## MANUFACTURER

MEDICA S.p.A. - Via degli Artigiani, 7 - 41036 Medolla (Modena) - ITALY  
Phone: +39 0535 51159 - [www.medica-spa.com](http://www.medica-spa.com) - [info@medica-spa.com](mailto:info@medica-spa.com)

## SINGLE REGISTRATION NUMBER (SRN)

IT-MF-000025691

## PRODUCT

CATHETERS AND ACCESSORIES FOR URODYNAMICS AND GI MANOMETRY

## INTENDED USE

the catheters and accessories for urodynamics and gastrointestinal manometry are non-active medical devices intended essentially for the execution of diagnostic procedures in Manometry and Urodynamics.

## PRODUCT CODES

See attached list

## REGULATION APPLIED

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April, 2017 (MDR)

## CONFORMITY ASSESSMENT ROUTE

Regulation (EU) 2017/745 - Annex IX, chapter I and III

## RISK CLASS - APPLICABLE RULE (MDR - Annex VIII)

Class IIa - Rule 5

## EC CERTIFICATE

MDR 00048-A

## EXPIRY DATE

May 31, 2028

## UNI CEI EN ISO 13485:2016 CERTIFICATE

3686 - M

## UNI CEI EN ISO 9001:2015 CERTIFICATE

3686 - A

## COMMON SPECIFICATIONS (CS) APPLIED

none

## NOTIFIED BODY

KIWA CERMET ITALIA S.p.A. - Via Cadriano 23 - 40057 Cadriano di Granarolo (Bologna) - ITALY - ID no.: 0476

Medica herewith declares, under its sole responsibility, that the products listed below meet the provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council of April 5, 2017, to be intended in the current version. All applicable documentation is retained at Medica head office.

## PLACE AND DATE OF ISSUE

Medolla (Modena), June 1, 2023

## APPROVED BY (NAME AND FUNCTION)



Eng. Luciano Fecondini  
Medica S.p.A. Board President

| DEVICE CODE  | DESCRIPTION                                                                                                                                                       | EMDN CLASSIFICATION | GMDN CLASSIFICATION | BASIC UDI-DI (MDR - Annex VI, Part C) | UDI-DI        |
|--------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|---------------------|---------------------------------------|---------------|
| 5E-9-100P    | Catetere <b>5E-9-100P</b> / <b>5E-9-100P</b> Catheter                                                                                                             | G010302             | 35053               | 803377232CAT-G0103G6                  | 8,03377E+12   |
| 5E-9-100D    | Catetere <b>5E-9-100D</b> / <b>5E-9-100D</b> Catheter                                                                                                             | G010302             | 35053               | 803377232CAT-G0103G6                  | 8033772320443 |
| 9E-12-100A   | Catetere <b>9E-12-100A</b> / <b>9E-12-100A</b> Catheter                                                                                                           | G010302             | 35053               | 803377232CAT-G0103G6                  | 8033772320450 |
| 5E-12-100    | Catetere per manometria esofagea 4 lumi elicoidali a 5 cm / Esophageal catheter 4 helicoidal channels at 5 cm                                                     | G010302             | 35053               | 803377232CAT-G0103G6                  | 8056992330108 |
| 5E-12-100H   | Catetere per manometria esofagea 4 lumi elicoidali a 5 cm / Esophageal catheter 4 helicoidals channels at 5 cm                                                    | G010302             | 35053               | 803377232CAT-G0103G6                  | 8056992330160 |
| 9E-12-100    | Catetere per manometria esofagea, 4 lumi radiali a 0 cm e 4 elicoidali a 5 cm / Esophageal catheter 8 channels, 4 radials at 0 and 4 helicoidal at 5 cm           | G010302             | 35053               | 803377232CAT-G0103G6                  | 8056992330115 |
| 9E-12-100L   | Catetere per manometria esofagea, 4 lumi a 1 cm da 0 cm e 4 a 5 cm / Esophageal catheter 8 channels, 4 at 1 cm from 0 and 4 at 5 cm                               | G010302             | 35053               | 803377232CAT-G0103G6                  | 8056992330122 |
| 9E-12-100H   | Catetere per manometria esofagea, 4 lumi radiali e 4 elicoidali a 5 cm / Esophageal catheter 8 channels, 4 radials and 4 helicoidal at 5 cm                       | G010302             | 35053               | 803377232CAT-G0103G6                  | 8056992330177 |
| 21E-14-100   | Caterere esofageo 20 canali per HRM / Esophageal catheter for HRM with 20 ports                                                                                   | G010302             | 35053               | 803377232CAT-G0103G6                  | 8056992330191 |
| 25HE-14-140A | Caterere esofageo 24 canali per HRM / Esophageal catheter for HRM with 24 ports                                                                                   | G010302             | 35053               | 803377232CAT-G0103G6                  | 8056992330207 |
| 5R-9-100CB   | Catetere <b>5R-9-100CB</b> / <b>5R-9-100CB</b> Catheter                                                                                                           | G020603             | 17745               | 803377232CAT-G0206GH                  | 8033772320467 |
| 5R-12-100CB  | Catetere <b>5R-12-100CB</b> / <b>5R-12-100CB</b> Catheter                                                                                                         | G020603             | 17745               | 803377232CAT-G0206GH                  | 8033772321471 |
| 5R-12-100VB  | Catetere <b>5R-12-100VB</b> / <b>5R-12-100VB</b> Catheter                                                                                                         | G020603             | 17745               | 803377232CAT-G0206GH                  | 8033772320474 |
| 9R-12-100CB  | Catetere <b>9R-12-100CB</b> / <b>9R-12-100CB</b> Catheter                                                                                                         | G020603             | 17745               | 803377232CAT-G0206GH                  | 8033772320481 |
| 9R-12-100V   | Catetere <b>9R-12-100V</b> / <b>9R-12-100V</b> Catheter                                                                                                           | G020603             | 17745               | 803377232CAT-G0206GH                  | 8033772320498 |
| 9R-12-100VB  | Catetere <b>9R-12-100VB</b> / <b>9R-12-100VB</b> Catheter                                                                                                         | G020603             | 17745               | 803377232CAT-G0206GH                  | 8033772320894 |
| 5R-12-100KB  | Catetere <b>5R-12-100KB</b> / <b>5R-12-100KB</b> Catheter                                                                                                         | G020603             | 17745               | 803377232CAT-G0206GH                  | 8033772321167 |
| 9G-12-130C   | Catetere <b>9G-12-130C</b> / <b>9G-12-130C</b> Catheter                                                                                                           | G020603             | 17745               | 803377232CAT-G0206GH                  | 8033772321389 |
| ISCHIA       | Catetere a 9 vie per manometria anorettale / 9-ways catheter for anorectal manometry                                                                              | G020603             | 17745               | 803377232CAT-G0206GH                  | 8033772323154 |
| 5R-12-100    | Catetere manometria anorettale 4 canali radiali a 0 cm e palloncino a -1 cm / Anorectal manometry catheter 4 radial channels at 0 cm and balloon at -1 cm         | G020603             | 17745               | 803377232CAT-G0206GH                  | 8056992330009 |
| 5R-12-100L   | Catetere manometria anorettale 4 canali elicoidali ad 1 cm e palloncino a -1 cm / Anorectal manometry catheter 4 helicoidal channels at 1 cm and balloon at -1 cm | G020603             | 17745               | 803377232CAT-G0206GH                  | 8056992330023 |

| DEVICE CODE   | DESCRIPTION                                                                                                                                                                                  | EMDN CLASSIFICATION | GMDN CLASSIFICATION | BASIC UDI-DI (MDR - Annex VI, Part C) | UDI-DI        |
|---------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|---------------------|---------------------------------------|---------------|
| 5R-12-100L3   | Catetere manometria anorettale 4 canali elicoidali ad 1 cm e palloncino a -3 cm / Anorectal manometry catheter 4 helicoidal channels at 1 cm and balloon at -3 cm                            | G020603             | 17745               | 803377232CAT-G0206GH                  | 8056992330030 |
| 5R-12-100LH   | Catetere manometria anorettale 4 canali elicoidali ad 1 cm dal pallone / Anorectal manometry catheter 4 helicoidal channels at 1 cm from the balloon                                         | G020603             | 17745               | 803377232CAT-G0206GH                  | 8056992330139 |
| 5R-12-100VB3  | Catetere manometria anorettale 4 canali radiali a 0 cm e palloncino a -3 cm / Anorectal manometry catheter 4 radial channels at 0 cm and balloon at -3 cm                                    | G020603             | 17745               | 803377232CAT-G0206GH                  | 8056992330016 |
| 5R-12-100VB3H | Catetere manometria anorettale 4 canali radiali a 0 cm e pallone a -3 cm / Anorectal manometry catheter 4 radial canals at 0 cm and balloon at -3 cm                                         | G020603             | 17745               | 803377232CAT-G0206GH                  | 8056992330146 |
| 9R-12-100     | Catetere manometria anorettale 4 canali elicoidali a 0.5 cm, 4 radiali e pallone a -1 cm / Anorectal manometry catheter with 4 helicoidal channels at 0.5 cm, 4 radial and balloon at -1 cm  | G020603             | 17745               | 803377232CAT-G0206GH                  | 8056992330047 |
| 9R-12-100KB   | Catetere manometria anorettale 8 canali elicoidali ad 1 cm a 0 cm e pallone a -2,5 cm / Anorectal manometry catheter 8 helicoidally channels at 1 cm at 0 cm and balloon at -2.5 cm          | G020603             | 17745               | 803377232CAT-G0206GH                  | 8056992331426 |
| 9R-12-100L    | Catetere manometria anorettale 8 canali elicoidali a 0.5 cm con pallone a -1 cm / Anorectal manometry catheter with 8 helicoidal channels at 0.5 cm and balloon at -1 cm                     | G020603             | 17745               | 803377232CAT-G0206GH                  | 8056992330085 |
| 9R-12-100L3   | Catetere manometria anorettale 8 canali elicoidali a 0.5 cm da 0 cm e con pallone a -3 cm / Anorectal manometry catheter with 8 helicoidal channels at 0.5 cm from 0 cm and balloon at -3 cm | G020603             | 17745               | 803377232CAT-G0206GH                  | 8056992330092 |
| 9R-12-100VB1  | Catetere manometria anorettale 8 canali radiali a 0 cm con pallone a -1 cm / Anorectal manometry catheter 8 radial channels at 0 cm and balloon at -1 cm                                     | G020603             | 17745               | 803377232CAT-G0206GH                  | 8056992330078 |
| 9R-12-100VB3  | Catetere manometria anorettale 8 canali radiali a 0 cm con pallone a -3 cm / Anorectal manometry catheter 8 radial channels at 0 cm and balloon at -3 cm                                     | G020603             | 17745               | 803377232CAT-G0206GH                  | 8056992330061 |
| 9R-12-100VB5  | Catetere manometria anorettale 8 canali radiali a 0 cm con pallone a -5 cm / Anorectal manometry catheter 8 radial channels at 0 cm and balloon at -5 cm                                     | G020603             | 17745               | 803377232CAT-G0206GH                  | 8056992330054 |
| 9R-12-100VB1H | Catetere manometria anorettale 8 canali radiali con pallone / Anorectal manometry catheter with radial 8 channels with balloon                                                               | G020603             | 17745               | 803377232CAT-G0206GH                  | 8056992330153 |
| 9R-12-100SR   | Catetere a 9 vie per Manometria Anorettale con Palloncino senza lattice, 12Fr / 9-ways Anorectal Manometry Catheter with Latex-free Balloon, 12 Fr                                           | G020603             | 17745               | 803377232CAT-G0206GH                  | 8033772323666 |
| 9C-12-130A    | Catetere a 9 vie per manometria del colon / 9-ways colon Manometry Catheter                                                                                                                  | G020603             | 17745               | 803377232CAT-G0206GH                  | 8033772327268 |
| 13R-14-100    | Catetere manometria anorettale 12 canali con pallone / Anorectal manometry catheter with radial 12 channels with balloon                                                                     | G020603             | 17745               | 803377232CAT-G0206GH                  | 8056992330184 |
| 2CYS-9        | Catetere <b>2CYS-9</b> / <b>2CYS-9</b> Catheter                                                                                                                                              | U050101             | 44675               | 803377232CAT-U0501MG                  | 8033772320542 |
| 2omni-9       | Catetere <b>2omni-9</b> / <b>2omni-9</b> Catheter                                                                                                                                            | U050101             | 44675               | 803377232CAT-U0501MG                  | 8033772320566 |
| 2CYS-6 PIG    | Catetere <b>2CYS-6 PIG</b> / <b>2CYS-6 PIG</b> Catheter                                                                                                                                      | U050101             | 44675               | 803377232CAT-U0501MG                  | 8033772320788 |
| 3omni-9       | Catetere <b>3omni-9</b> / <b>3omni-9</b> Catheter                                                                                                                                            | U050101             | 44675               | 803377232CAT-U0501MG                  | 8033772320818 |
| 2CYS-9E       | Catetere <b>2CYS-9E</b> / <b>2CYS-9E</b> Catheter                                                                                                                                            | U050101             | 44675               | 803377232CAT-U0501MG                  | 8033772320979 |
| 3omni-9E      | Catetere <b>3omni-9E</b> / <b>3omni-9E</b> Catheter                                                                                                                                          | U050101             | 44675               | 803377232CAT-U0501MG                  | 8033772320986 |

| DEVICE CODE | DESCRIPTION                                                                                                                                             | EMDN CLASSIFICATION | GMDN CLASSIFICATION | BASIC UDI-DI (MDR - Annex VI, Part C) | UDI-DI        |
|-------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|---------------------|---------------------------------------|---------------|
| 1TIE-9      | Catetere <b>1TIE-9 / 1TIE-9</b> Catheter                                                                                                                | U050101             | 44675               | 803377232CAT-U0501MG                  | 8033772321020 |
| 2omni-9R    | Catetere <b>2omni-9R</b>                                                                                                                                | U050101             | 44675               | 803377232CAT-U0501MG                  | 8033772321303 |
| 2omni-8P    | Catetere <b>2omni-8P / 2omni-8P</b> Catheter                                                                                                            | U050101             | 44675               | 803377232CAT-U0501MG                  | 8033772321440 |
| 3omni-8P    | Catetere <b>3omni-8P / 3omni-8P</b> Catheter                                                                                                            | U050101             | 44675               | 803377232CAT-U0501MG                  | 8033772321457 |
| 3omni-8UP   | Catetere <b>3omni-8UP / 3omni-8UP</b> Catheter                                                                                                          | U050101             | 44675               | 803377232CAT-U0501MG                  | 8033772321464 |
| 2OMNI-8PH   | Catetere <b>2omni-8pH / 2omni-8pH</b> Catheter                                                                                                          | U050101             | 44675               | 803377232CAT-U0501MG                  | 8033772325530 |
| CPS-D-6MX   | Set di cateteri a due vie 6 Fr ed una via 5 Fr ( 2CYS-6LE + 1AR-5TI ) / Set of a 2-way catheter , 6 Fr and a 1-way catheter , 5Fr (2CYS-6LE + 1AR-5TI)  | U050101             | 44675               | 803377232CAT-U0501MG                  | 8033772325554 |
| CPS-D-6MX9  | Set di cateteri a 2 vie , 6 Fr e 9 Fr (2CYS-6LE + 2AR-9TE) / Set of a 2-ways catheter, 6 Fr and 9 Fr (2CYS-6LE + 2AR-9TE)                               | U050101             | 44675               | 803377232CAT-U0501MG                  | 8033772328197 |
| CPS-D-8MX   | Set di cateteri a 2 vie , 8 Fr e ad 1 via , 5 Fr (2CYS-8PE + 1AR-5TI) / Set of a 2-ways catheter , 8 Fr and a 1-way catheter , 5Fr (2CYS-8PE + 1AR-5TI) | U050101             | 44675               | 803377232CAT-U0501MG                  | 8033772325561 |
| CPS-D-8MX12 | Set di cateteri a 2 vie , 8 Fr e 12 Fr (2CYS-8LE + 2AR-12TE) / Set of a 2-ways catheter, 8 Fr and 12 Fr (2CYS-8LE + 2AR-12TE)                           | U050101             | 44675               | 803377232CAT-U0501MG                  | 8033772328203 |
| CPS-D-12MX  | Set di cateteri a 2 vie , 6 Fr e 12 Fr (2CYS-6LE + 2AR-12TE) / Set of a 2-ways catheter, 6 Fr and 12 Fr (2CYS-6LE + 2AR-12TE)                           | U050101             | 44675               | 803377232CAT-U0501MG                  | 8033772327145 |
| CPS-S-MX    | Set di 3 cateteri ad 1 via (1BF-8P + 1PF-5PE + 1AR-5TI) / Set of three catheters , 1 way (1BF-8P + 1PF-5PE + 1AR-5TI)                                   | U050101             | 44675               | 803377232CAT-U0501MG                  | 8033772325578 |
| 2CYS-6      | Catetere <b>2CYS-6 / 2CYS-6</b> Catheter                                                                                                                | U050201             | 44675               | 803377232CAT-U0502MJ                  | 8033772320528 |
| 2CYS-6L     | Catetere <b>2CYS-6L / 2CYS-6L</b> Catheter                                                                                                              | U050201             | 44675               | 803377232CAT-U0502MJ                  | 8033772320535 |
| 2omni-6     | Catetere <b>2omni-6 / 2omni-6</b> Catheter                                                                                                              | U050201             | 44675               | 803377232CAT-U0502MJ                  | 8033772320559 |
| 1PF-4       | Catetere <b>1PF-4 / 1PF-4</b> Catheter                                                                                                                  | U050201             | 44675               | 803377232CAT-U0502MJ                  | 8033772320597 |
| 1BF-9       | Catetere <b>1BF-9 / 1BF-9</b> Catheter                                                                                                                  | U050201             | 44675               | 803377232CAT-U0502MJ                  | 8033772320702 |
| 2PF-6M      | Catetere 2 vie Mercier solo per studio del flusso pressorio 2PF-6M / 2PF-6M 2-WAY Mercier catheter for pressure flow study                              | U050201             | 44675               | 803377232CAT-U0502MJ                  | 8033772320757 |
| 1PF-4L PIG  | Catetere <b>1PF-4L PIG / 1PF-4L PIG</b> Catheter                                                                                                        | U050201             | 44675               | 803377232CAT-U0502MJ                  | 8033772320948 |
| 1PF-4E      | Catetere <b>1PF-4E / 1PF-4E</b> Catheter                                                                                                                | U050201             | 44675               | 803377232CAT-U0502MJ                  | 8033772321037 |
| 2CYS-6LE    | Catetere <b>2CYS-6LE / 2CYS-6LE</b> Catheter                                                                                                            | U050201             | 44675               | 803377232CAT-U0502MJ                  | 8033772321075 |

| DEVICE CODE | DESCRIPTION                                                                                                                             | EMDN CLASSIFICATION | GMDN CLASSIFICATION | BASIC UDI-DI (MDR - Annex VI, Part C) | UDI-DI        |
|-------------|-----------------------------------------------------------------------------------------------------------------------------------------|---------------------|---------------------|---------------------------------------|---------------|
| 2CYS-6P     | Catetere <b>2CYS-6P</b> / <b>2CYS-6P</b> Catheter                                                                                       | U050201             | 44675               | 803377232CAT-U0502MJ                  | 8033772321426 |
| 2omni-6NP   | Catetere <b>2omni-6NP</b> / <b>2omni-6NP</b> Catheter                                                                                   | U050201             | 44675               | 803377232CAT-U0502MJ                  | 8033772321433 |
| 2CYS-8P     | Catetere <b>2CYS-8P</b> / <b>2CYS-8P</b> Catheter                                                                                       | U050201             | 44675               | 803377232CAT-U0502MJ                  | 8033772323123 |
| SET PF      | SET PF                                                                                                                                  | U050201             | 44675               | 803377232CAT-U0502MJ                  | 8033772323314 |
| 2CYS-8PE    | Catetere a 2 vie in PVC , 8Fr / 2-ways catheter in PVC, 8Fr                                                                             | U050201             | 44675               | 803377232CAT-U0502MJ                  | 8033772325585 |
| 2CYS-8PES   | Catetere a 2 vie in PVC morbido con linea d'estensione Blu, 8Fr / 2-way catheter for cystometry - PFS in PVC, soft, 8 Fr with Blue line | U050201             | 44675               | 803377232CAT-U0502MJ                  | 8056992331341 |
| 1BF-8P      | Catetere a 1 via in PVC , 8Fr per infusione vescicale / 1-way catheter for bladder filling in PVC, 8 Fr                                 | U050201             | 44675               | 803377232CAT-U0502MJ                  | 8033772325592 |
| 1PF-5PE     | Catetere ad 1 via per pressione vescicale , in PVC lungo 1,8 m, 5 Fr / 1-way catheter for bladder pressure in PVC 1,8 m long, 5 Fr      | U050201             | 44675               | 803377232CAT-U0502MJ                  | 8033772325608 |
| 2TIE-8P     | Catetere a 2 vie con punta Coudè in PVC , 8 Fr / Double way catheter with Coudè tip in PVC 8 Fr diameter                                | U050201             | 44675               | 803377232CAT-U0502MJ                  | 8033772325615 |
| 2PP-9L      | Catetere <b>2PP-9L</b> / <b>2PP-9L</b> Catheter                                                                                         | U050301             | 44675               | 803377232CAT-U0503ML                  | 8033772320580 |
| 5PPV-9      | Catetere <b>5PPV-9</b> / <b>5PPV-9</b> Catheter                                                                                         | U050301             | 44675               | 803377232CAT-U0503ML                  | 8033772320801 |
| 2omni-6N    | Catetere <b>2omni-6N</b> / <b>2omni-6N</b> Catheter                                                                                     | U050301             | 44675               | 803377232CAT-U0503ML                  | 8033772320887 |
| 1AR-12      | Catetere <b>1AR-12</b> / <b>1AR-12</b> Catheter                                                                                         | U050402             | 44675               | 803377232CAT-U0504MN                  | 8033772320610 |
| 1AR-12SC    | Catetere <b>1AR-12SC</b> / <b>1AR-12SC</b> Catheter                                                                                     | U050402             | 44675               | 803377232CAT-U0504MN                  | 8033772320627 |
| 2AR-9       | Catetere <b>2AR-9</b> / <b>2AR-9</b> Catheter                                                                                           | U050402             | 44675               | 803377232CAT-U0504MN                  | 8033772320634 |
| 2AR-12L     | Catetere 2AR-12L / 2AR-12L Catheter                                                                                                     | U050402             | 44675               | 803377232CAT-U0504MN                  | 8033772320641 |
| 2AR-12SM    | Catetere <b>2AR-12SM</b> / <b>2AR-12SM</b> Catheter                                                                                     | U050402             | 44675               | 803377232CAT-U0504MN                  | 8033772320658 |
| 2AR-12SL    | Catetere <b>2AR-12SL</b> / <b>2AR-12SL</b> Catheter                                                                                     | U050402             | 44675               | 803377232CAT-U0504MN                  | 8033772320665 |
| 2AR-12MX    | Catetere <b>2AR-12MX</b> / <b>2AR-12MX</b> Catheter                                                                                     | U050402             | 44675               | 803377232CAT-U0504MN                  | 8033772320672 |
| 2AR-9T      | Catetere <b>2AR-9T</b> / <b>2AR-9T</b> Catheter                                                                                         | U050402             | 44675               | 803377232CAT-U0504MN                  | 8033772321501 |
| 2AR-9TE     | Catetere <b>2AR-9TE</b> / <b>2AR-9TE</b> Catheter                                                                                       | U050402             | 44675               | 803377232CAT-U0504MN                  | 8033772321327 |

| DEVICE CODE | DESCRIPTION                                                                                                                                                 | EMDN CLASSIFICATION | GMDN CLASSIFICATION | BASIC UDI-DI (MDR - Annex VI, Part C) | UDI-DI        |
|-------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|---------------------|---------------------------------------|---------------|
| 2AR-12T     | Catetere <b>2AR-12T</b> / <b>2AR-12T</b> Catheter                                                                                                           | U050402             | 44675               | 803377232CAT-U0504MN                  | 8033772320924 |
| 1AR-5T      | Catetere <b>1AR-5T</b> / <b>1AR-5T</b> Catheter                                                                                                             | U050402             | 44675               | 803377232CAT-U0504MN                  | 8033772321013 |
| 2AR-9E      | Catetere <b>2AR-9E</b> / <b>2AR-9E</b> Catheter                                                                                                             | U050402             | 44675               | 803377232CAT-U0504MN                  | 8033772321051 |
| 2AR-9TS     | Catetere <b>2AR-9TS</b> / <b>2AR-9TS</b> Catheter                                                                                                           | U050402             | 44675               | 803377232CAT-U0504MN                  | 8033772321211 |
| 2AR-12TS    | Catetere <b>2AR-12TS</b> / <b>2AR-12TS</b> Catheter                                                                                                         | U050402             | 44675               | 803377232CAT-U0504MN                  | 8033772321228 |
| 2AR-12TE    | Catetere <b>2AR-12TE</b> / <b>2AR-12TE</b> Catheter                                                                                                         | U050402             | 44675               | 803377232CAT-U0504MN                  | 8033772321334 |
| 1AR-5TC     | Catetere <b>1AR-5TC</b> / <b>1AR-5TC</b> Catheter                                                                                                           | U050402             | 44675               | 803377232CAT-U0504MN                  | 8033772321396 |
| 2AR-9TM     | Catetere <b>2AR-9TM</b> / <b>2AR-9TM</b> Catheter                                                                                                           | U050402             | 44675               | 803377232CAT-U0504MN                  | 8033772321310 |
| 1AR-5I      | Catetere di Urodinamica monolume per il rilevamento della Pressione Addominale con Introdotto. Palloncino in polisoprene 7 x 20 mm                          | U050402             | 44675               | 803377232CAT-U0504MN                  | 8033772327619 |
| 1AR-5TI     | Catetere Rettale monolume con linea, palloncino e introdotto / 1-way Rectal Catheter, 5 Fr with line, balloon and introducer                                | U050402             | 44675               | 803377232CAT-U0504MN                  | 8033772325394 |
| 1AR-5IS     | Catetere Rettale monolume 5Fr con linea, palloncino tagliato e nuovo introdotto / 1-way Rectal Catheter 5Fr with line, balloon with slit and new introducer | U050402             | 44675               | 803377232CAT-U0504MN                  | 8056992331419 |
| CAV SET     | Linea CAV SET / CAV SET line                                                                                                                                | U0505               | 44675               | 803377232CAT-U0505MQ                  | 8056992331310 |
| 1RB-12B1    | Catetere addominale ad un palloncino / Abdominal catheter with 1 balloon                                                                                    | U070301             | 44675               | 803377232CAT-U0703MW                  | 8056992331327 |
| 2RB-12B2    | Catetere addominale a due palloncini / Abdominal catheter with 2 balloons                                                                                   | U070301             | 44675               | 803377232CAT-U0703MW                  | 8056992331334 |
| SC3         | Rubinetto 3 vie con luer lock SC3 / SC3 3-WAY stop-cock with luer lock                                                                                      | U0580               | 44675               | 803377232CAT-U0580N6                  | 8033772320245 |
| EXT-180/SC3 | Prolunga very-low compliance con rubinetto 3 vie EXT-180/SC3 / EXT-180/SC3 Very-Low compliance Extension line with 3-WAY stop-cock                          | U0580               | 44675               | 803377232CAT-U0580N6                  | 8033772320252 |
| EXT-180     | Prolunga <b>EXT-180</b> very-low compliance / <b>EXT-180</b> Very-Low compliance Extension line                                                             | U0580               | 44675               | 803377232CAT-U0580N6                  | 8033772320269 |
| QUICK SBC   | Set pompa peristaltica QUICK SBC / QUICK SBC Peristaltic Pump Set                                                                                           | U0580               | 35833               | 803377232CAT-U0580N6                  | 8033772320283 |
| QUICK SP    | Sezione sottopompa QUICK SP per pompa peristaltica Pico QUICK / QUICK SP Subpump Segm. PharMed for peristaltic pump Pico QUICK                              | U0580               | 35833               | 803377232CAT-U0580N6                  | 8033772320290 |
| L-CYS       | Linea per cistomanometria <b>L-CYS</b> / <b>L-CYS</b> Cystomanometry line                                                                                   | U0580               | 44675               | 803377232CAT-U0580N6                  | 8033772320313 |
| ADA – MF    | Adattatore cono maschio con luer lock femmina <b>ADA – MF</b> / <b>ADA – MF</b> Male Cone Adapter with female luer lock                                     | U0580               | 44675               | 803377232CAT-U0580N6                  | 8033772320337 |

| DEVICE CODE | DESCRIPTION                                                                                                                                                  | EMDN CLASSIFICATION | GMDN CLASSIFICATION | BASIC UDI-DI (MDR - Annex VI, Part C) | UDI-DI        |
|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|---------------------|---------------------------------------|---------------|
| SC2         | Rubinetto 2 vie con luer lock SC2 / SC2 2 WAY stop-cock with luer lock                                                                                       | U0580               | 44675               | 803377232CAT-U0580N6                  | 8033772320375 |
| WTP         | Deflussore <b>WTP SET</b> per pompa peristaltica / <b>WTP SET</b> Infusion Set for Peristaltic Pump                                                          | U0580               | 35833               | 803377232CAT-U0580N6                  | 8033772320405 |
| QCI         | Deflussore capillare quadruplo <b>QCI / QCI</b> Quadruple Capillary Infusion set                                                                             | U0580               | 44675               | 803377232CAT-U0580N6                  | 8033772320764 |
| WTP/UP SET  | Deflussore <b>WTP/UP SET</b> con spezzone pompa in PVC e capillare per UPP / <b>WTP/UP SET</b> Infusion Line Set with pump segment PVC and capillary for UPP | U0580               | 35833               | 803377232CAT-U0580N6                  | 8033772320863 |
| SCI Set     | Deflussore capillare singolo <b>SCI Set / SCI Set</b> - Single Capillary Infusion set                                                                        | U0580               | 44675               | 803377232CAT-U0580N6                  | 8033772320870 |
| EXT-180B    | Prolunga blu <b>EXT-180B / EXT-180B</b> Blue Extension Line                                                                                                  | U0580               | 44675               | 803377232CAT-U0580N6                  | 8033772320993 |
| EXT-180R    | Prolunga rossa <b>EXT-180R / EXT-180R</b> RedExtension Line                                                                                                  | U0580               | 44675               | 803377232CAT-U0580N6                  | 8033772321006 |
| EXT-180Y    | Prolunga gialla <b>EXT-180Y / EXT-180Y</b> Yellow Extension Line                                                                                             | U0580               | 44675               | 803377232CAT-U0580N6                  | 8033772321143 |
| E34-180     | Prolunga Ø 3 x 4 mm <b>E34-180 / E34-180</b> Extension Line Ø 3 x 4 mm                                                                                       | U0580               | 44675               | 803377232CAT-U0580N6                  | 8033772321297 |
| NRV         | Valvola di non ritorno <b>NRV</b> con FLL e MLL / <b>NRV</b> Non return valve with FLL and MLL                                                               | U0580               | 35833               | 803377232CAT-U0580N6                  | 8033772321402 |
| WTP-LT2     | Set pompa per urodinamica LT 3011 / Pump tubing set LT 3011                                                                                                  | U0580               | 35833               | 803377232CAT-U0580N6                  | 8033772325646 |
| EXT-150TB   | Linea di estensione, 150 cm, trasparente con connettori Blu / Extension line, 150 cm, transparent with Blue connectors                                       | U0580               | 44675               | 803377232CAT-U0580N6                  | 8033772328500 |
| EXT-150TR   | Linea di estensione, 150 cm, trasparente con connettori Rossi / Extension line, 150 cm, transparent with Red connectors                                      | U0580               | 44675               | 803377232CAT-U0580N6                  | 8033772328517 |
| EXT-150TY   | Linea di estensione, 150 cm, trasparente con connettori Gialli / Extension line, 150 cm, transparent with Yellow connectors                                  | U0580               | 44675               | 803377232CAT-U0580N6                  | 8033772328524 |
| M90349      | Adattatore Luer Lock Maschio/Maschio                                                                                                                         | U0580               | 35833               | 803377232CAT-U0580N6                  | 8033772329279 |
| SF3         | Set per riempimento linee dei trasduttori di pressione / set for the filling of the pressure lines                                                           | U0580               | 44675               | 803377232CAT-U0580N6                  | 8033772329262 |
| MD023       | Pressure transducer                                                                                                                                          | U0580               | 35833               | 803377232CAT-U0580N6                  | 8056992332713 |
| S15656      | Catetere MMS G-84300 - 9 Fr. / MMS G-84300 catheter - 9 Fr.                                                                                                  | G010302             | 35053               | 803377232CAT-G0103G6                  | 8056992332928 |
| S15657      | Catetere MMS G-84301 - 9 Fr. / MMS G-84301 catheter - 9 Fr.                                                                                                  | G010302             | 35053               | 803377232CAT-G0103G6                  | 8056992332935 |
| S15658      | Catetere MMS G-88402 - 12 Fr. / MMS G-88402 catheter - 12 Fr.                                                                                                | G010302             | 35053               | 803377232CAT-G0103G6                  | 8056992332942 |
| S15659      | Catetere MMS G-88403 - 12 Fr. / MMS G-88403 catheter - 12 Fr.                                                                                                | G010302             | 35053               | 803377232CAT-G0103G6                  | 8056992332959 |
| S15661      | Catetere MMS G-84480 - 12 Fr. / MMS G-84480 catheter - 12 Fr.                                                                                                | G020603             | 17745               | 803377232CAT-G0206GH                  | 8056992332966 |
| S15662      | Catetere MMS G-84481 - 12 Fr. / MMS G-84481 catheter - 12 Fr.                                                                                                | G020603             | 17745               | 803377232CAT-G0206GH                  | 8056992332973 |
| S15663      | Catetere MMS G-84482 - 12 Fr. / MMS G-84482 catheter - 12 Fr.                                                                                                | G020603             | 17745               | 803377232CAT-G0206GH                  | 8056992332980 |

| DEVICE CODE | DESCRIPTION                                                                                                                      | EMDN<br>CLASSIFICATION | GMDN<br>CLASSIFICATION | BASIC UDI-DI (MDR -<br>Annex VI, Part C) | UDI-DI        |
|-------------|----------------------------------------------------------------------------------------------------------------------------------|------------------------|------------------------|------------------------------------------|---------------|
| S15664      | Catetere MMS G-84383 - 9 Fr. / MMS G-84383 catheter - 9 Fr.                                                                      | G020603                | 17745                  | 803377232CAT-G0206GH                     | 8056992332997 |
| S15665      | Catetere MMS G-84384 - 9 Fr. / MMS G-84384 catheter - 9 Fr.                                                                      | G020603                | 17745                  | 803377232CAT-G0206GH                     | 8056992333000 |
| S15666      | Catetere MMS G-88485 - 12 Fr. / MMS G-88485 catheter - 12 Fr.                                                                    | G020603                | 17745                  | 803377232CAT-G0206GH                     | 8056992333017 |
| S15667      | Catetere MMS G-88486 - 12 Fr. / MMS G-88486 catheter - 12 Fr.                                                                    | G020603                | 17745                  | 803377232CAT-G0206GH                     | 8056992333024 |
| S15668      | Catetere MMS G-88487 - 12 Fr. / MMS G-88487 catheter - 12 Fr.                                                                    | G020603                | 17745                  | 803377232CAT-G0206GH                     | 8056992333031 |
| S15670      | Catetere MMS G-88489 - 12 Fr. / MMS G-88489 catheter - 12 Fr.                                                                    | G020603                | 17745                  | 803377232CAT-G0206GH                     | 8056992333048 |
| S15671      | Catetere MMS G-88490 - 12 Fr. / MMS G-88490 catheter - 12 Fr.                                                                    | G020603                | 17745                  | 803377232CAT-G0206GH                     | 8056992333055 |
| S15516      | Catetere MMS U-73901 - 9 Fr. / MMS U-73901 catheter - 9 Fr.                                                                      | U050101                | 44675                  | 803377232CAT-U0501MG                     | 8056992333062 |
| S15516SL    | Catetere MMS U-73901SL - 9 Fr. / MMS U-73901SL catheter - 9 Fr.                                                                  | U050101                | 44675                  | 803377232CAT-U0501MG                     | 8056992333079 |
| S15536      | Catetere MMS U-72602 - 6 Fr. / MMS U-72602 catheter - 6 Fr.                                                                      | U050101                | 44675                  | 803377232CAT-U0501MG                     | 8056992333086 |
| S15690      | Set di cateteri per urodinamica - MMS U-72003 (U-73901 + U-71501) /<br>Urodynamic Catheter Set - MMS U-72003 (U-73901 + U-71501) | U050101                | 44675                  | 803377232CAT-U0501MG                     | 8056992333093 |
| S15778      | Catetere MMS U-73909 RING - 9 Fr. / MMS U-73909 RING catheter - 9 Fr.                                                            | U050101                | 44675                  | 803377232CAT-U0501MG                     | 8056992333109 |
| S15924      | Catetere MMS U-72606 - 6 Fr. / MMS U-72606 catheter - 6 Fr.                                                                      | U050101                | 44675                  | 803377232CAT-U0501MG                     | 8056992333116 |
| S15924SL    | Catetere MMS U-72606SL - 6 Fr. / MMS U-72606SL catheter - 6 Fr.                                                                  | U050101                | 44675                  | 803377232CAT-U0501MG                     | 8056992333123 |
| S15538      | Catetere MMS U-72902 -9 Fr. / MMS U-72902 catheter -9 Fr.                                                                        | U050101                | 44675                  | 803377232CAT-U0501MG                     | 8056992333130 |
| S15689      | Set di cateteri per urodinamica - MMS U-72002 (U-72902 + U-71501) /<br>Urodynamic Catheter Set - MMS U-72002 (U-72902 + U-71501) | U050101                | 44675                  | 803377232CAT-U0501MG                     | 8056992333147 |
| S15927      | Set di cateteri per urodinamica - MMS U-72004 (U-72603 + U-71501) /<br>Urodynamic Catheter Set - MMS U-72004 (U-72603 + U-71501) | U050101                | 44675                  | 803377232CAT-U0501MG                     | 8056992333154 |
| S15537      | Catetere MMS U-72603 - 6 Fr. / MMS U-72603 catheter - 6 Fr.                                                                      | U050201                | 44675                  | 803377232CAT-U0502MJ                     | 8056992333161 |
| S15537SL    | Catetere MMS U-72603SL - 6 Fr. / MMS U-72603SL catheter - 6 Fr.                                                                  | U050201                | 44675                  | 803377232CAT-U0502MJ                     | 8056992333178 |
| S15538SL    | Catetere MMS U-72902SL -9 Fr. / MMS U-72902SL catheter -9 Fr.                                                                    | U050201                | 44675                  | 803377232CAT-U0502MJ                     | 8056992333185 |
| S15551      | Catetere MMS U-72605 - 6 Fr. / MMS U-72605 catheter - 6 Fr.                                                                      | U050201                | 44675                  | 803377232CAT-U0502MJ                     | 8056992333192 |
| S15552      | Catetere MMS U-71402 - 4 Fr. / MMS U-71402 catheter - 4 Fr.                                                                      | U050201                | 44675                  | 803377232CAT-U0502MJ                     | 8056992333208 |
| S15855      | Catetere MMS U-62802 - 8 Fr. (10) / MMS U-62802 catheter - 8 Fr. (10)                                                            | U050201                | 44675                  | 803377232CAT-U0502MJ                     | 8056992333215 |
| S15526      | Catetere MMS U-71501 - 7,5 Fr. / MMS U-71501 catheter - 7.5 Fr.                                                                  | U050402                | 44675                  | 803377232CAT-U0504MN                     | 8056992333222 |
| S15926      | Catetere MMS U-72210 - 12 Fr. / MMS U-72210 catheter - 12 Fr.                                                                    | U050402                | 44675                  | 803377232CAT-U0504MN                     | 8056992333239 |
| S15926SL    | Catetere MMS U-72210SL - 12 Fr. / MMS U-72210SL catheter - 12 Fr.                                                                | U050402                | 44675                  | 803377232CAT-U0504MN                     | 8056992333246 |
| S15766      | Set di risciacquo a 4 vie - MMS / MMS 4 - way flushingset                                                                        | U0580                  | 44675                  | 803377232CAT-U0580N6                     | 8056992333253 |
| S15812      | Flow reducer set UPP, SU - Set per riduttore di flusso (profilo pressione uretrale)                                              | U0580                  | 44675                  | 803377232CAT-U0580N6                     | 8056992333260 |

| REVISION HYSTORY |            |            |                                                                                                                                                                                                                                                                                                  |               |                                                                  |                |
|------------------|------------|------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|------------------------------------------------------------------|----------------|
| REV              | REF        | VALID FROM | CODES INSERTED                                                                                                                                                                                                                                                                                   | CODES DELETED | OTHER CHANGE                                                     | AUTHOR         |
| 00               | CDP010623A | 01/06/2023 | NA                                                                                                                                                                                                                                                                                               | NA            | First release                                                    | Laura Calza    |
| 01               | CDP010623A | 16/06/2023 | NA                                                                                                                                                                                                                                                                                               | NA            | Change of conformity assessment route; added GMDN classification | Laura Calza    |
| 02               | CDP161222A | 05/12/2023 | MD023                                                                                                                                                                                                                                                                                            | NA            | NA                                                               | Laura Calza    |
| 03               | CDP110923A | 29/04/2024 | S15656, S15657, S15658, S15659, S15661, S15662, S15663, S15664, S15665, S15666, S15667, S15668, S15670, S15671, S15516, S15516SL, S15536, S15690, S15778, S15924, S15924SL, S15537, S15537SL, S15538, S15538SL, S15551, S15552, S15689, S15855, S15927, S15926, S15926SL, S15526, S15766, S15812 | NA            | NA                                                               | Mauro Dell'Ovo |