DECLARATION OF CONFORMITY

This EU Declaration of Conformity is issued under the sole responsiblility of Medex Instrumenten Service.

We hereby declare that the CE-marked medical devices identified in the table below, are marketed in compliance with REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices. In accordance with the conformity assessment route for Class I products, the technical documentation set out in Annexes II and III of REGULATION (EU) 2017/745, has been drawn up.

Product group	EMDN code	Classification & rule MDR Annex VIII	Basic UDI-DI
Dilators	L	Class 1, Rule 5	872026124R5DIL

Products/variants that are part of this product-group are identified in the appendix of this Declaration.

In addition, the QMS of Medex Instrumenten Service is certified by Dekra to EN ISO 13485:2016:

Certification number	Scope
2260145	Design, develop, manufacture, repair, modification and distribution of surgical instruments

Almere, 25-08-2025



Lianda Mulder-Timmerman
Quality Assurance & Regulatory Affairs / PRRC

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APPENDIX OF THE DECLARATION

EMDN description: Surgical probes, Rectal
EMDN code: L04100202
Basic UDI-DI: 872026124R5DIL0186
Intended use: Rectal dilator, reusable - A surgical instrument designed to dilate the anal sphincter and canal when the size of the anal opening may interfere with its function or the passage of an examining instrument. This is a reusable device.

Product name	Article code	UDI-DI
Rectal probe 25mm diam.	ME05-004	08720261243368
Rectal probe 29mm diam.	ME05-005	08720261241753
Rectal probe 31mm diam.	ME05-006	08720261243375
Rectal probe 33mm diam.	ME05-007	08720261243559
Steel rectal probe	ME05-015	08720261241098
Rectal probe Ø 21mm	ME05-016-21	08720261241593
Rectal probe Ø 23mm	ME05-016-23	08720261242828
Rectal probe Ø 25mm	ME05-016-25	08720261245584
Rectal probe Ø 27mm	ME05-016-27	08720261241609
Rectal probe Ø 29mm	ME05-016-29	08720261241104
Rectal probe Ø 31mm	ME05-016-31	08720261245591
Rectal probe Ø 33mm	ME05-016-33	08720261241616

EMDN description: Urethral dilators
EMDN code: L06050101
Basic UDI-DI: 872026124R5DIL0288
Intended use: Urethral dilator, reusable - A slender, solid or hollow, flexible or semi-flexible, surgical instrument designed to dilate the urethra, mainly to treat strictures of the urethra, to facilitate the extraction of stones (renal calculi), and/or to facilitate catheter placement. It is typically made of metal or plastics and is available in a range of sizes. Urethral bougies are also used for urethral dilatation. This is a reusable device.

Article code	Product name	UDI-DI
Urological speculum urethroplasty	ME04-019	08720261243115
Dilator for urology (urethra) 2mm	ME05-022-02	08720261243177
Dilator for urology (urethra) 3mm	ME05-022-03	08720261243184
Dilator for urology (urethra) 4mm	ME05-022-04	08720261243191
Dilator for urology (urethra) 5mm	ME05-022-05	08720261243207
Dilator for urology (urethra) 6mm	ME05-022-06	08720261243214
Dilator for urology (urethra) 7mm	ME05-022-07	08720261243221
Dilator for urology (urethra) 8mm	ME05-022-08	08720261243238
Dilator for urology (urethra) 9mm	ME05-022-09	08720261243245
Dilator for urology (urethra) 10mm	ME05-022-10	08720261243252
Dilator for urology (urethra) 11mm	ME05-022-11	08720261243269
Dilator for urology (urethra) 12mm	ME05-022-12	08720261243276

Dilator for urology (urethra) 13mm	ME05-022-13	08720261243283
Dilator for urology (urethra) 14mm	ME05-022-14	08720261243290
Dilator for urology (urethra) 15mm	ME05-022-15	08720261243306
Dilator for urology (urethra) 16mm	ME05-022-16	08720261243313

EMDN description: Gynaecological surgery probes
EMDN code: L050905
Basic UDI-DI: 872026124R5DIL038A
Intended use: Uterine manipulator, reusable - A hand-held, manually-operated, surgical instrument designed to mechanically manipulate the position of the uterus during a gynaecological intervention (e.g., laparoscopic hysterectomy), to enable uterine control and improved visibility of the pelvic anatomy. The device typically consists of a probe which is positioned within an introduction sheath/handpiece. This is a reusable device intended to be sterilized prior to use.

Product name	**Article code**	**UDI-DI**
Hysterophore RVS	ME04-013	08720261242187