



DECLARATION OF CONFORMITY
(According to Annex IV)

<i>Manufacturer:</i>	Mizra Medical Ltd VAT No. 513346130 21 Hasadna Street, Industrial Park, Holon, 5881411, Israel Tel: 972-3-5506645, Fax: 972-3-5561105 SRN # IL-MF-000015502
<i>EU Authorized Representative:</i>	AF Pharma Service Europe SL ES-AR-000018076 Muntaner 281, Barcelona, 08021, España +34684988915 info@afpharmaservice.com
<i>Product Name</i>	<i>Male External Catheter and accessories</i> <i>As listed below</i>
<i>Medical Device Classification:</i> <i>(MDR EU 2017/745 Annex VIII,</i> <i>Chapter III, 4.1)</i>	Class I (Rule 1)
<i>Male External Catheter and accessories - for single use.</i> <i>Male External Catheter intended for collection of urine in males suffering from incontinence.</i> <i>Diverts urine from penis to extension tubing and urinary collection bags.</i> <i>Male External Catheter can be used only for external use and can be used for up to 24 hours.</i> <i>Therefore, these products classified as Class I medical Devices</i>	
<i>Conformity Assessment Route:</i>	Annex II and Annex III
<i>Status</i>	Self-declared

"Mizra Medical Ltd" declares, under its own responsibility, that the above-mentioned medical device is conforming to the GSPR of the Medical Device Regulation (EU) 2017/745 and conforming to the applicable rules of product and process. Technical File and supporting documentation are retained under the premises of the Manufacturer at disposition of the Competent Authorities. The manufacturer is the only responsible for this Declaration of Conformity. "Mizra Medical Ltd" has developed an internal procedure for the vigilance system of the medical devices according to (EU) 2017/745. "Mizra Medical Ltd" complies with the requested harmonized norms and standards for marketing their products in the EU and Israel*.

Validity of this declaration of conformity: 365 days from the date of issue

21 Hasadna St., Holon, Israel



Mizra Medical

Helping People in Challenging Situations

Signature:
Dror Mizra
CEO

MIZRA MEDICAL LTD,
I.D # 513346130

Date:

October 11, 2024

Basic UDI-DI	Product name and Description	Manufacturer's Part No.
	Mec – Latex	
7290018953006	MEN'S EXTERNAL CATHETER- LATEX-diam 20mm (30 Units)	10141520
7290018953013	MEN'S EXTERNAL CATHETER- LATEX-diam 25mm (30 Units)	10141525
7290018953020	MEN'S EXTERNAL CATHETER- LATEX-diam 30mm (30 Units)	10141530
7290018953037	MEN'S EXTERNAL CATHETER- LATEX-diam 35mm (30 Units)	10141535
7290018953044	MEN'S EXTERNAL CATHETER- LATEX-diam 40mm (30 Units)	10141540
7290018953051	Kit catheter Ø 20mm + hydrocolloid strip L (30 Units)	12841520
7290018953068	Kit catheter Ø 25mm + hydrocolloid strip XL (30 Units)	12841525
7290018953075	Kit catheter Ø 30mm + hydrocolloid strip L (30 Units)	12841530
7290018953082	Kit catheter Ø 35mm + hydrocolloid strip XL (30 Units)	12841535
7290018953099	Kit catheter Ø 40mm + hydrocolloid strip L (30 Units)	12841540
7290018953273	Male External Catheter size 20 mm Single Side ADHESIVE STRIP (Blue)	12111220
7290018953280	Male External Catheter size 25 mm Single Side ADHESIVE STRIP (Blue)	12111225
7290018953297	Male External Catheter size 30 mm Single Side ADHESIVE STRIP (Blue)	12111230
7290018953303	Male External Catheter size 35 mm Single Side ADHESIVE STRIP (Blue)	12111235
7290018953310	Male External Catheter size 40 mm Single Side ADHESIVE STRIP(Blue)	12111240
7290018953327	Male External Catheter size 25 mm DABBLE SIDE ADHESIVE STRIP-FOAM (Red)	12211225
7290018953334	Male External Catheter size 30 mm DABBLE SIDE ADHESIVE STRIP-FOAM (Red)	12211230
7290018953341	Male External Catheter size 35 mm DABBLE SIDE ADHESIVE STRIP-FOAM (Red)	12211235
7290018953358	UROINDAS PACK 1 COLEC + 1 TIRA 25MM XXXXXXXX Male external 30mm +hystrip	12300225
7290018953365	UROINDAS PACK 1 COLEC + 1 TIRA 30MM 6509004 Male external 30mm +hystrip	12300230
7290018953372	UROINDAS PACK 1 COLEC+1TIRA 35MM 6509005 Male external 35mm + hystrip	12300235
7290018953402	Male External Catheter PLAIN WHITE BAG 30pcs size 15 mm	10140015
7290018953419	Male External Catheter PLAIN WHITE BAG 30pcs size 20 mm	10140020
7290018953426	Male External Catheter PLAIN WHITE BAG 30pcs size 25 mm	10140025
7290018953433	Male External Catheter PLAIN WHITE BAG 30pcs size 30 mm	10140030
7290018953440	Male External Catheter PLAIN WHITE BAG 30pcs size 35 mm	10140035
7290018953457	Male External Catheter PLAIN WHITE BAG 30pcs size 40 mm	10140040
7290018953907	Male External Catheter PLAIN WHITE BAG 100pcs size 15 mm	10370015
7290018953709	Male External Catheter PLAIN WHITE BAG 100pcs size 20 mm	10370020

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7290018953914	Male External Catheter PLAIN WHITE BAG 100pcs size 25 mm	10370025
7290018953815	Male External Catheter PLAIN WHITE BAG 100pcs size 30 mm	10370030
7290018953716	Male External Catheter PLAIN WHITE BAG 100pcs size 35 mm	10370035
7290018953617	Male External Catheter PLAIN WHITE BAG 100pcs size 40 mm	10370040
7290018953464	Male External Catheter size 15 mm (Bulk)	10350015
7290018953471	Male External Catheter size 20 mm (Bulk)	10350020
7290018953488	Male External Catheter size 25 mm (Bulk)	10350025
7290018953495	Male External Catheter size 30 mm (Bulk)	10350030
7290018953501	Male External Catheter size 35 mm (Bulk)	10350035
7290018953518	Male External Catheter size 40 mm (Bulk)	10350040
7290018953525	Male External Catheter size 15 + Hydrocolloid strip flow pack Box 30pcs	12300015
7290018953532	Male External Catheter size 20 + Hydrocolloid strip flow pack Box 30pcs	12300020
7290018953549	Male External Catheter size 25 + Hydrocolloid strip flow pack Box 30pcs	12300025
7290018953556	Male External Catheter size 30 + Hydrocolloid strip flow pack Box 30pcs	12300030
7290018953563	Male External Catheter size 35 + Hydrocolloid strip flow pack Box 30pcs	12300035
7290018953570	Male External Catheter size 40 + Hydrocolloid strip flow pack Box 30pcs	12300040
Silicon Standard MEC		
7290018953631	Silicon Standard MEC Self-adhesive Size 25 mm	15648025
7290018953648	Silicon Standard MEC Self-adhesive Size 29 mm	15648029
7290018953655	Silicon Standard MEC Self-adhesive Size 32 mm	15648032
7290018953662	Silicon Standard MEC Self-adhesive Size 36 mm	15648036
7290018953679	Silicon Standard MEC Self-adhesive Size 41 mm	15648041
7290018953686	Silicon Special MEC Self-adhesive Size 25 mm	15848025
7290018953693	Silicon Special MEC Self-adhesive Size 29 mm	15848029
7290018953723	Silicon Special MEC Self-adhesive Size 32 mm	15848032
7290018953730	Silicon Special MEC Self-adhesive Size 36 mm	15848036
7290018953747	Silicon Special MEC Self-adhesive Size 41 mm	15848041
7290018953754	Silicon Natural MEC Size 25 mm	15548025
7290018953761	Silicon Natural MEC Size 29 mm	15548029
7290018953778	Silicon Natural MEC Size 32 mm	15548032
7290018953785	Silicon Natural MEC Size 36 mm	15548036
7290018953792	Silicon Natural MEC Size 41 mm	15548041
7290018953105	DABBLE SIDE ADHESIVE STRIP-FOAM (30 Units)	19921503
7290018953389	Bi-adhesive hydrocolloid strip PLAIN WHITE BOX 12x1,8x0,1cm	19930003
7290018953808	Bi-adhesive hydrocolloid strip 12x1,8x0,1cm 30 Units	19931830
7290018953396	MALE URINARY SHEATH BI ADHESIVE STRIP, PLAIN WHITE BAG OF 30 PCS	19920002
7290018953228	MALE URINARY SHEATH Single Side ADHESIVE STRIP, PLAIN WHITE BAG OF 30 PCS	19920030
7290018953600	Z STRAP 3 in 1 FIXING SYSTEM for urine bag, tube,c	19802103
7290018953594	Safe & Secure- Reusable foam strap- box 5 pcs-60x40x40cm-moq 1 carton	19801002



Reference	Title
ISO 14971	Medical devices- Application of risk management to medical devices
(EU) 2017/745	Medical devices regulation (MDR)
GSPR-1	General Safety and Performance Requirements – Performance and Safety
GSPR-7	General Safety and Performance Requirements – Packaging, transport, storage
ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
ISO 9001	QUALITY MANAGEMENT SYSTEMS
ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer

*List of International Standards