DECLARATION OF CONFORMITY TO THE MEDICAL DEVICE DIRECTIVE

MDD 93/42EEC as amended by 2007/47EC

Authorized Representative.

Biometrix SRO
Vicenzy 16S
Samorin, 93101
Slovakia
SRN: SK-AR-000002253

Notified body:

TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 MÜNCHEN
Germany

Manufacturer Name and Address:

Biometrix LIMITED
4 Kiryat Mada
9145000 Jerusalem
Israel
SRN: IL-MF-000010010

Importer:

Biometrix SRO
Vicenzy 16S
Samorin , 93101
Slovakia
SRN:SK-IM-000003112

Certificate No: G1 002374 0005 **(Exp. Date)**: 2024-05-26

Product family: Drainage Catheters

Products sub-groups: Foley catheters including Suprapubic sets

Classification: Class IIb, Rule 5

Intended Use: For urological bladder drainage and bladder irrigation via urethra or stoma

GMDN Code: 34917

CND Code: U0401,U010106,U010102,U010104,U010105,V03010299

Applicable Standards: 11-005 REV01 list of standards TF 7.01

Herewith to declare that:
Above-mentioned product complies with Annex II excluding 4 of the Medical Device Directive, MDD 93/42/EEC as amended by 2007/47/EC. All supporting documentation is held by the manufacturer.
Biometrix LIMITED is exclusively responsible for the Declaration of Conformity.

List of devices is enclosed in Appendix A.

Zuzana Vavreková — 30.10.2021

RA Manager — Date

Appendix A - List of devices:

List of Devices – Foley catheters:

Device description	Ref #
8Fr 2 Way Silicone Foley Catheter,Nelaton Tip	MN-0008
10Fr 2 Way Silicone Foley Catheter,Nelaton Tip	MN-0010
12Fr 2 Way Silicone Foley Catheter,Nelaton Tip	MN-0012
14Fr 2 Way Silicone Foley Catheter,Nelaton Tip	MN-0014
16Fr 2 Way Silicone Foley Catheter,Nelaton Tip	MN-0016
18Fr 2 Way Silicone Foley Catheter,Nelaton Tip	MN-0018
20Fr 2 Way Silicone Foley Catheter,Nelaton Tip	MN-0020
22Fr 2 Way Silicone Foley Catheter,Nelaton Tip	MN-0022
24Fr 2 Way Silicone Foley Catheter,Nelaton Tip	MN-0024
6Fr Foley Catheter With Temperature Sensor	MN-0106
8Fr Foley Catheter With Temperature Sensor	MN-0108
10fr Foley Catheter With Temperature Sensor	MN-0110
12fr Foley Catheter With Temperature Sensor	MN-0112
14fr Foley Catheter With Temperature Sensor	MN-0114
16fr Foley Catheter With Temperature Sensor	MN-0116
18fr Foley Catheter Wi Temperature Sensor	MN-0118
16Fr 3 Way Silicone Foley Catheter Nelaton	MN-0316
18Fr 3 Way Silicone Foley Catheter Nelaton	MN-0318
20Fr 3 Way Silicone Foley Catheter Nelaton	MN-0320
22Fr 3 Way Silicone Foley Catheter Nelaton	MN-0322
24Fr 3 Way Silicone Foley Catheter Nelaton	MN-0324
6Fr 2 Way Silicone Foley Catheter Stylet Sterile	MN-0406
8Fr 2 Way Silicone Foley Catheter Stylet Sterile	MN-0408
10Fr 2Way Silicone Foley Catheter Stylet Sterile	MN-0410
10 Fr 2 Way Silicone Foley Catheter Tiemann	MN-1010
12 Fr 2 Way Silicone Foley Catheter Tiemann	MN-1012
14 Fr 2 Way Silicone Foley Catheter Tiemann	MN-1014
16 Fr 2 Way Silicone Foley Catheter Tiemann	MN-1016
18 Fr 2 Way Silicone Foley Catheter Tiemann	MN-1018
20 Fr 2 Way Silicone Foley Catheter Tiemann	MN-1020
22 Fr 2 Way Silicone Foley Catheter Tiemann	MN-1022
24 Fr 2 Way Silicone Foley Catheter Tiemann	MN-1024
16Fr 3 Way Silicone Foley Catheter Couvelaire	MN-2316
18Fr 3 Way Silicone Foley Catheter Couvelaire	MN-2318
20Fr 3 Way Silicone Foley Catheter Couvelaire	MN-2320
22Fr 3 Way Silicone Foley Catheter Couvelaire	MN-2322
24Fr 3 Way Silicone Foley Catheter Couvelaire	MN-2324
16Fr 3 Way Silicone Foley Catheter Dufour	MN-3316
18Fr 3 Way Silicone Foley Catheter Dufour	MN-3318
20Fr 3 Way Silicone Foley Catheter Dufour	MN-3320
22Fr 3 Way Silicone Foley Catheter Dufour	MN-3322

24Fr 3 Way Silicone Foley Catheter Dufour	MN-3324
16Fr 3 Way Silicone Foley Catheter Mercier	MN-4316
18Fr 3 Way Silicone Foley Catheter Mercier	MN-4318
20Fr 3 Way Silicone Foley Catheter Mercier	MN-4320
22Fr 3 Way Silicone Foley Catheter Mercier	MN-4322
24Fr 3 Way Silicone Foley Catheter Mercier	MN-4324
16Fr 3Way Staggered Nelaton Tip	MN-5316
18Fr 3Way Staggered Nelaton Tip	MN-5318
20Fr 3Way Staggered Nelaton Tip	MN-5320
22Fr 3Way Staggered Nelaton Tip	MN-5322
24Fr 3Way Staggered Nelaton Tip	MN-5324
SUPRAPUBIC PUNCTURE SET 14fr	MN-SP914
SUPRAPUBIC INTR.SET SELDINGER 12Fr	MN-SPS12
SUPRAPUBIC INTR.SET SELDINGER 14Fr	MN-SPS14
SUPRAPUBIC INTR.SET SELDINGER 16Fr	MN-SPS16

End of List