



EC DECLARATION OF CONFORMITY

Manufacturer: Toruńskie Zakłady Materiałów Opatrunkowych S.A. (TZMO S.A.)

Address: Toruń, ul. Żółkiewskiego 20/26, POLAND

Product: **MATOSSET operation kits sterile**

Types/versions: Specialist set, Baby set, ACL set, Amputation set, Limb amputation set, Angiography set, Angiography - embolisation set, Arthroscopy set, Bariatric set, Biopsy set, Caesarean section set, Catheter set, Breast surgery set, Thoracic surgery set, General surgery set, Plastic surgery set, Cystoscopy set, Dermatology set, Set for OP-field disinfection, Dialysis set, Dialysis set A, Dialysis set B, Pericardial drainage set, Electrotherapy set, Endoscopy set, HD set "start", HD set "stop", Cricothyrotomy set, Set for coronary catheterisation and PTCA, Craniotomy set, Laparoscopy set, Gynecologic laparoscopy set, Laparotomy set, Abscess incision set, Nephrostomy set, Circumcision set, Abdominal-perineal set, Carpal tunnel syndrome set, Hand set, Hand/foot set, Gynaecology set, Cardiac surgery set, Cardiology set, Knee set, Lower limb set, Spine surgery, Laryngology set, Ilizarov method operation set, Neurosurgical set, Ophthalmology set, Orthopaedic set, Hernia set, Shoulder set, Hip set, Foot set, Jaw operation set, Strumectomy set, Urology and gynaecology set, Urology set, Urology set PCNL, Urology set TUR, Urology set URS, Cataract set, Varix set, Drip infusion set, Delivery set, Prostatectomy set, Prostatectomy set BCF, Dialysis connection set, Postpartum suturing set, Postpartum suturing set, Tomography set, Tracheostomy set, Suture removal set, Umbilical cord clamp removal set, Skin staple removal set, Vasectomy set, Central line insertion set, Intravitreal injection set, Lumbar puncture set, Pacemaker implantation set, Suture set, IV cannula set, Dialysis disconnection set, Dressing change set, Anaesthesia set, Set for spinal anesthesia, II specialist jaw operation set, Dressing set, Universal set, Paediatric universal set, Universal set with accessories, Knee arthroscopy set, Catheter set for haemodialysis, Central venous catheter set, Trauma surgery set, Basic cardiac surgery set, Lobectomy set, Emergency medicine set, Clinical oncology set, Graft dressing set, Oral surgery set, Pelvic/lumbar spine surgery set, Collarbone surgery set, Acute dialysis set, Dialysis catheter removal set, Vertical isolation set, Dialysis catheter placement set, Venous port catheter insertion set

Classification: II a

Scope: the above mentioned product conforms to the Essential Requirements of Council Directive 93/42/EEC concerning Medical Devices (date of issue: 14.06.1993 with further amendments).

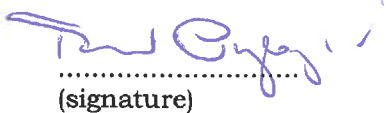
Notified body: Conformity assessments have been carried out in accordance with Annex VII and Annex V of Directive 93/42 / EEC. The above mentioned products are covered under the CE Mark certificate No TNP/MDD/0230/4722/2018-001 (Annex V of Directive 93/42/EEC), issued by TUV NORD Polska Sp. z o.o., (2274).

The above mentioned product conforms to the following harmonised standards:

PN EN ISO 13485:2016, PN EN 285:2016, PN EN 556-1:2002, PN EN 1041+A1:2013, PN EN 1422:2014, PN EN ISO 10993-1:2010, PN EN ISO 10993-5:2009, PN EN ISO 10993-7:2009, PN EN ISO 11135:2014, PN EN ISO 11138-2:2017, PN EN ISO 11138-3:2017, PN EN ISO 11140-1:2015, PN EN ISO 11607-1:2017, PN EN ISO 11607-2:2017, PN EN ISO 11737-1:2018, PN EN ISO 11737-2:2010, PN EN 14079:2004, PN EN ISO 14971:2012, PN EN ISO 15223-1:2017, PN EN ISO 17665-1:2008, PN EN 62366-1:2015.

TZMO S.A. is registered to ISO 9001:2015, certificate No PL008673/P (issued by Bureau Veritas Polska Sp. z o.o.) and ISO 13485:2016, certificate No 283504-2019-AQ-POL-FINAS (issued by DNV GL Business Assurance Finland Oy Ab).

Toruń, June 5th 2019
(place and date of issue)


(signature)

Tomasz Przybylski
(full name)

Proxy TZMO SA
(position)


(signature)

Agnieszka Górna
(full name)

Member of the Board TZMO SA
(position)