

MANAGEMENT SYSTEM CERTIFICATE

Certificate No:
283504-2019-AQ-POL-FINAS

Initial certification date:
21 June 2018

Valid:
30 January 2020 - 28 February 2022

This is to certify that the management system of

Toruńskie Zakłady Materiałów Opatrunkowych S.A.

ul. Żółkiewskiego 20/26, 87-100 Toruń, Poland
and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:
ISO 13485:2016

This certificate is valid for the following scope:

Design, manufacture, sterilisation, sales and distribution of medical devices: surgical sets, surgical instruments and equipment, surgical clothing and OP-drapes, gauze products, disposable and reusable devices. Design, manufacture, sales and distribution of medical devices including medical devices for people with incontinence, packaging for sterilisation of medical devices and plasters and adhesive tapes, dressing meshes, elastic bandages, P.O.P. bandages. Manufacture and sales of semi-finished knitted products for implantable medical devices. Printing and packaging of medical packaging materials. Production of covers for medical devices. Ethylene oxide and steam sterilisation services.

Place and date:
Espoo, 30 January 2020



For the issuing office:
DNV GL - Business Assurance
Keilasatama 5, 02150 Espoo, Finland

Kimmo Haarala
Management Representative



Certificate No: 283504-2019-AQ-POL-FINAS
Place and date: Espoo, 30 January 2020

Appendix to Certificate

Toruńskie Zakłady Materiałów Opatrunkowych S.A.

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
Toruńskie Zakłady Materiałów Opatrunkowych S.A.	ul. Żółkiewskiego 20/26, 87-100 Toruń, Poland	Sales and distribution of medical devices including medical devices for people with incontinence.
Plastica Sp. z o.o.	Frydrychowo 55, 87-410 Kowalewo Pomorskie, Poland	Design, manufacture, sterilisation and sales of medical devices: operation kits, surgical instruments and equipment, disposable and reusable devices. Design, manufacture and sales of medical devices for people with incontinence and packaging for sterilisation of medical devices. Printing and packaging of medical packaging materials. Production of covers for medical devices. Ethylene oxide and steam sterilisation services.
Centrum Logistyczne TZMO S.A.	ul. Przelot 39, 87-100 Toruń, Poland	Storage and distribution of medical devices.
SENI S.A.	ul. Generała Sikorskiego 66, 87-300 Brodnica, Poland	Design, manufacture and sale of medical devices for people with incontinence.
TZMO Tkalnie Żelów S.A.	ul. Zachodnia 25, 97-425 Żelów, Poland	Design, manufacture and sales of gauze medical devices, surgical clothing and OP-drapes, plasters and adhesive tapes, dressing meshes, elastic bandages, P.O.P bandages. Manufacture and sales of semi-finished knitted products for vascular prostheses, skull bone prostheses, orbital bone prostheses, urological tapes, hernia meshes, ligament and tendon prostheses.