

CANCELLED AND SUSPENDED CERTIFICATES

Certified Subject	Certificate No.	Standard	Scope of certification	Date of issue	Date of cancellation/suspension	Reason of cancellation/suspension
FaiveleyTech Nitra s.r.o., Slovak Republic	E-0132/22	ISO 14001:2015	Production of technical plastic products by injection and assembly technology	December 8th, 2022	September 14th, 2023	Client's request
THE WAVE INNOVATION GROUP SRLS	M-0536/22	EN ISO 13485:2016	design, management of production and marketing of sterile implantable medical devices	December 9th, 2022	November 30th, 2023	Client's request
Sanima, s.r.o., Slovak Republic	Q-0885/23	ISO 9001:2015	Purchase, sale and consulting in the field of packaging materials and technology	March 6th, 2023	January 1st, 2024	Client's request
Nissens Cooling Solutions North SK, s.r.o., Slovak Republic	Q-0845/22 E-0392/22	ISO 9001:2015 ISO 14001:2015	Aluminium welding	December 5th, 2022	January 31st, 2024	Client's request
KOMA Kardioprax, s.r.o., Slovak Republic	Q-0819A,B/23	ISO 9001:2015	Only sk version: poskytovanie zdravotníckej starostlivosti v špecializačných odboroch pediatrika kardiológia, klinická imunológia a alergológia	October 1st, 2023	January 31st, 2024	Client's request
Power Service Int. s.r.o., Slovak Republic	Q-0851/23 E-0396/23 S-0315/23	ISO 9001:2015 ISO 14001:2015 ISO 45001:2018	Sales of electrical devices, equipment and related services (including project management, engineering, installation, upgrading and maintenance of electrical devices), civil works and refurbishment works	May 28th, 2023	April 15th, 2024	Client's request
BIONEER Corporation, Republic of Korea	M-0515/23	EN ISO 13485:2016	Design, development, manufacture, sales and distribution of in-vitro molecular diagnostic for specimen collection kit from human and in-vitro molecular diagnostic used in the extraction of nucleic acids from human specimen. Manufacture, sales and distribution of molecular diagnostic products used in the in-vitro diagnosis of infectious diseases.	April 3rd, 2023	September 26th, 2024	Client's request
Prvá ekologická s.r.o., Slovak Republic	Q-0841/22 E-0387/22	ISO 9001:2015 ISO 14001:2015	Waste management	July 1st, 2022	10.06.2025	Client's request
3D Smile USA dba 3D Predict, USA	M-0537/23	EN ISO 13485:2016	Design and development, order processing, case set up and planning and distribution of the orthodontic aligners	January 15th, 2023	January 10th, 2025	Client's request

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DABO Industry Co, LTD, Korea	2020-MDD/QS-110 NB Confirmation letter No. MIT/2024/P118	Council Directive 93/42/EEC	auditory stimulator brand name: brain on model: db-2000a	September 14th, 2020	January 21st, 2025	Client's request
IMGSA GROUPE INDUSTRIE PHARMACEUTIQUE, Algeria	M-0471/23	ISO 13485:2016	MANUFACTURING AND SALE OF NON-ACTIVE NON- IMPLANTABLE DEVICES FOR WOUND AND SKIN CARE: SURGICAL AND EXAMINATION LATEX PRE-POWDERED GLOVES, POWDER FREE LATEX GLOVES AND NITRILE GLOVES	9.6.2023	23.07.2025	SA was not performed
SAS Company for syringes manufacturing, Egypt	2018-MDD/QS-011 Confirmation letter No. LUL/2023/P010	Council Directive 93/42/EHS	Sterile Medical Syringes with Needles	13.1.2018	23.1.2025	Termination of contract
IPM Chirana Inc.	M-0551/23	ISO 13485:2015	PRODUCTION, SALES AND SERVICING OF ACTIVE (NON- IMPLANTABLE) MEDICAL DEVICES: SERVOVENTILATORS	9.10.2023	20.2.2025	Client's request
MIT Group s.r.o., Slovak Republic	M-0568/24	ISO 13485:2016	STORAGE AND DISTRIBUTION OF MEDICAL DEVICES	26.03.2024	27.09.2025	SA was not performed
JSC "DIAKON-DS", Russia	M-0402/24	ISO 13485:2016	Design, development, manufacturing, distribution and servicing of In-Vitro Diagnostic Medical Devices: reagents, kits of reagents, analyzers	26.04.2024	12.1.2026	Geopolitical situation SA was not performed
DST s.r.o. Dental Stará Turá, Slovak republic	M-0220/24	ISO 13485:2016	PRODUCTION, SALES AND SERVICE OF ACTIVE DENTAL DEVICES - DENTAL UNITS	16.05.2024	10.06.2025	Client's request
STAV MD s.r.o., Třebíšov, Slovak Republic	Q-0818/24 E-0376/24 S-0301/24	ISO 9001:2015 ISO 14001:2015 ISO 45001:2018	Zatepľovanie bytových domov, ploché strechy, rekonštrukcie obytných a účelových budov.	02.10.2024	20.08.2025	Client's request
AGERA PRINT s.r.o.	Q-0831/24	ISO 9001:2015	Výroba a prodej polygrafických produktů.	29.11.2024	01.11.2025	Client's request
3 Energy s.r.o., Slovak Republic	Q-0805/22 E-0370/22 S-0296/22	ISO 9001:2015 ISO 14001:2015 ISO 45001:2018	CONSTRUCTION, ASSEMBLY AND ELECTRICAL INSTALLATION WORKS, BUSINESS ACTIVITY, SUPPLY AND IMPLEMENTATION OF ENERGY SAVING DEVICES	23.09.2022	22.9.2025	Client's request
ELMONT SLOVAKIA s.r.o. Slovak Republic	Q-0667/22 Q-0292/22	ISO 9001:2015 ISO 14001:2015	MANUFACTURE, INSTALLATION, REPAIR AND MAINTENANCE OF ELECTRICAL DEVICES INSTALLATION AND REPAIR OF MEASURING AND CONTROL TECHNIQUES	23.08.2022	11.09.2025	Client's request

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Germ s. r. o.	Q-0854/23 M-0480/23	ISO 9001:2015 ISO 13485:2016	DESIGN AND DEVELOPMENT, MANUFACTURE AND SERVICE OF FILTRATION AND DISINFECTION EQUIPMENT DESIGN AND DEVELOPMENT, PRODUCTION AND SERVICE OF ACTIVE MEDICAL DEVICES FOR DISINFECTION AND STERILIZATION, OZONE STERILIZERS WITH AIR REGENERATION	19.09.2023	Certification suspended on 02.12.2025 until 30.06.2026	Client's request
DyAnsys India Private Limited, India	2019-MDD/QS-098 Confirmation letter no. MIT/2024/P110	Council Directive 93/42/EEC	Neurostimulation Device Brand name: AuriStim® Variant: AuriStim®	16.12.2019	31.12.2025	Withdrawn on Client's request
Strojstav CM s. r. o., Slovak Republic	Q-0560/24	ISO 9001:2015	DEVELOPMENT, PRODUCTION, SALES AND SERVICES OF EQUIPMENT FOR THE PRODUCTION AND TRANSPORT OF MORTAR AND CONCRETE MIXTURES, PLASTERING MACHINES, CONCRETE PUMPS, MACHINES FOR APPLYING SCREEDS, MIXERS, METALURGICAL MACHINERY AND OTHER PRODUCTION OF WELDED AND MACHINED METAL PRODUCTS	21.06.2024	Certification suspended on 02.01.2026 until 02.06.2026	Nebol vykonaný dozorný audit Certifikát pozastavený od 2.1.2026 – 2.6.2026
Toplan Co., Ltd., Republic of Korea	M-0500/24	ISO 13485:2016	DESIGN AND DEVELOPMENT, MANUFACTURING, SALES AND DISTRIBUTION OF NON-ACTIVE MEDICAL DEVICE FOR STERILE DENTAL IMPLANT SYSTEMS AND NON-STERILE DENTAL SURGICAL INSTRUMENTS	13.05.2024	22.01.2026	SA was not performed
Mass For Medical Necessities, Egypt	2019-MDD/QS-052 NB Confirmation Letter No. MIT/2024/P109	Council Directive 93/42/EEC	Sterile Hypodermic Syringe for Single Use Trade name: Mass Syringe	25.5.2021	9.3.2026	SA was not performed Termination of contract

Prepared by: Eva Rýdlová

Date: 10.03.2026

Approved by: Dr. Katarína Tomin Srdošová

Date: 10.03.2026