

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 or 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	Certification suspended on December 16th, 2024 until June 16th, 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	January 15th, 2023	January 10th, 2025	Client's request

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			the orthodontic aligners			
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 13485:2015	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	Certification suspended on 22.01.2025 until 22.07.2025	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 13485:2015	STORAGE AND DISTRIBUTION OF MEDICAL DEVICES	26.03.2024	Certification suspended on 26.03.2025 until 26.09.2025	SA was not performed
JSC "DIAKON-DS", Russia	M-0402/24	ISO 13485:2015	Design, development, manufacturing, distribution and servicing of In-Vitro Diagnostic Medical Devices: reagents, kits of reagents, analyzers	26.04.2024	Certification suspended on 14.05.2025 until 28.11.2025	Geopolitical situation
DST s.r.o. Dental Stará Turá, Slovak republic	M-0220/24	ISO 13485:2015	PRODUCTION, SALES AND SERVICE OF ACTIVE DENTAL DEVICES - DENTAL UNITS	16.05.2024	10.06.2025	Client's request
STAV MD s.r.o., Trebišov, Slovenská republika	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

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Date: 01.11.2025
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