EU Declaration of Conformity

Name of the manufacturer

DIAGNOSTICS s.r.o.

Address of the manufacturer

Hodská 68 , 924 01 Galanta, Slovakia
ID: 35871181
TAX ID: 2021281394
SRN: SK-MF-000038255

Intended purpose

Identification of microorganisms

This is to certify that the following *in vitro* diagnostic devices have been assessed for conformity of the product, manufacturing process, technical documentation and quality system with the EU Regulation 2017/746 IVDR laying down technical requirements for *in vitro* diagnostic medical devices, as amended. The product is safe, effective and suitable for the intended use specified by the manufacturer.

The technical documentation for the conformity of the product has been drawn up in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council, Annexes II and III, the procedure laid down in Article 17 and Annex IV has been used for the declaration of conformity, and the manufacturer has affixed the CE marking to the product in accordance with Annex V. The EU declaration of conformity shall be issued under the sole responsibility of the manufacturer for the benefit of the competent authorities, customers and economic entities.

Classification: **class A non-sterile** (rule no. 5a)

The manufacturer has an established, maintained and certified quality system according to:
ISO 9001:2016, certificate No.: Q-0489/23, exp. 9.12.2026
13485:2016, certificate No.: M-0200/23, exp. 9.12.2026

certified body: 3 EC International as

The following documents were used for the conformity assessment:

Regulation (EU) 2017/746 - Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices / ISO 9001:2016 Quality management system - Requirements / CSN EN ISO 13485:2016 Medical devices - Quality management system / NV No. 56/2015 Coll. on technical requirements for *in vitro* diagnostic medical devices / CSN EN ISO 14971:2020 Medical devices - Application of risk management to medical devices / CSN EN 13612:2002 Functional evaluation of *in vitro* diagnostic medical devices / CSN EN ISO 18113- 1:2012 *In vitro* diagnostic medical devices - Information provided by the manufacturer (labelling). Part 1: Concepts, definitions and general requirements / EN ISO 18113-2:2012 *In vitro* diagnostic medical devices - Information provided by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use / EN ISO 15223- 1:2017 Medical devices - Medical device labels, markings and information provided by medical devices - Part 1: General requirements / MEDDEV 2.12.-1 Rev 8 January 2013 Guidance on the medical device vigilance system

Basic UDI-DI	Product name	Ref.
85880079261001sp26	GN24 sp	1001sp
85880079261001fpYU	GN24 fp	1001fp
85880079261002sp2B	GP24 sp	1002sp
85880079261002fpYZ	GP24 fp	1002 fp
85880079261003332	ENC 8	1003
8588007926100434	NEISS 8	1004
8588007926100536	YST 8	1005
85880079261006sp2X	ENT16 sp	1006sp
85880079261006fpZM	ENT16 fp	1006fp
85880079261007sp34	ST16 sp	1007sp
85880079261007fpZS	ST16 fp	1007 fp
8588007926200135	OXI	2001
8588007926200137	COLI	2002
8588007926200339	PYR	2003
858800792620043B	VP	2004
858800792620053D	ONP	2005
858800792620063F	HIP	2006
858800792620073H	INDOXYL	2007
858800792620093M	TRB	2009
858800792630013C	Paraffin oil	3001
858800792630023E	IND reagent	3002
858800792630033G	PYR reagent	3003
858800792630043J	VP reagent	3004
858800792630053L	NIT reagent	3005
858800792630063N	HIP reagent	3006
858800792630073Q	PHE reagent	3007
858800792630083S	PHS reagent	3008
858800792630093U	DMACA reagent	3009
858800792630113F	Matrix for mass spectrometry	3011
858800792640013K	Suspension medium	4001
858800792650013S	Zn (zinc dust)	5001
85880079266001-500SR	ARA-Arabinose	6001-500
85880079266001-50SB	ARA-Arabinose	6001-50
85880079266002-500T4	CEL-Cellobiose	6002-500
85880079266002-50SJ	CEL-Cellobiose	6002-50
85880079266003-500TF	ERY-erytritol	6003-500
85880079266003-50SR	ERY-erytritol	6003-50
85880079266004-500TS	GAL- Galactose	6004-500
85880079266004-50SY	GAL- Galactose	6004-50
85880079266005-500U5	GLU - Glucose	6005-500
85880079266005-50T7	GLU- Glucose	6005-50
85880079266006-500UG	INO- Inositol	6006-500
85880079266006-50TE	INO- Inositol	6006-50
85880079266007-500UT	LAC-Lactose	6007-500

85880079266007-50TM	LAC-Lactose	6007-50
85880079266008-500V6	MNS- Mannose	6008-500
85880079266008-50TU	MNS- Mannose	6008-50
85880079266009-500VH	Melibióza MLB	6009-500
85880079266009-50U3	Melibióza MLB	6009-50
85880079266010-500ST	MLT- Maltose	6010-500
85880079266010-50SF	MLT- Maltose	6010-50
85880079266011-500T6	MLZ- Melezitose	6011-500
85880079266011-50SN	MLZ- Melezitose	6011-50
85880079266012-500TH	RAF- Raffinose	6012-500
85880079266012-50SV	RAF- Raffinose	6012-50
85880079266013-500TU	RHA- Rhamnose	6013-500
85880079266013-50T4	RHA- Rhamnose	6013-50
85880079266014-500U7	RIB- Ribose	6014-500
85880079266014-50TB	RIB- Ribose	6014-50
85880079266015-500UJ	SOR-sorbitol	6015-500
85880079266015-50TJ	SOR-sorbitol	6015-50
85880079266016-500UV	SUC- Sucrose	6016-500
85880079266016-50TR	SUC- Sucrose	6016-50
85880079266017-500V8	TRE- Trehalose	6017-500
85880079266017-50TY	TRE- Trehalose	6017-50
85880079266018-500VK	XYL-xylose	6018-500
85880079266018-50U7	XYL-xylose	6018-50
85880079266019-500VW	NIT-Nitrate	6019-500
85880079266019-50UE	NIT-Nitrate	6019-50
85880079266020-500T8	PEP-peptón	6020-500
85880079266020-50SS	PEP-peptón	6020-50
85880079266021-500TK	Urea	6021-500
85880079266021-50SZ	Urea	6021-50
85880079266026-500VA	X factor	6026-500
85880079266026-50U4	X factor	6026-50
85880079266027-500VM	V factor	6027-500
85880079266027-50UB	V factor	6027-50
85880079266028-500VY	Factor X + V	6028-500
85880079266028-50UJ	Factor X + V	6028-50

Signature: 10.12.2023
DIAGNOSTICS s.r.o.
Petr Sára
COO