

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 | Parafínový olej | 3001 |
| 858800792630023E | IND činidlo | 3002 |
| 858800792630033G | Činidlo PYR | 3003 |
| 858800792630043J | VP činidlo | 3004 |
| 858800792630053L | NIT činidlo | 3005 |
| 858800792630063N | HIP činidlo | 3006 |
| 858800792630073Q | Činidlo PHE | 3007 |
| 858800792630083S | PHS činidlo | 3008 |
| 858800792630093U | Činidlo DMACA | 3009 |
| 858800792630113F | Zmeniť. matica pre hmotnostné spektrum | 3011 |
| 858800792640013K | Závesné médiá | 4001 |
| 858800792650013S | Zn (zinkový prach) | 5001 |
| 85880079266001-500SR | ARA-arabinóza | 6001-500 |
| 85880079266001-50SB | ARA-arabinóza | 6001-50 |
| 85880079266002-500T4 | CEL celobióza | 6002-500 |
| 85880079266002-50SJ | CEL celobióza | 6002-50 |
| 85880079266003-500TF | ERY-erytritol | 6003-500 |
| 85880079266003-50SR | ERY-erytritol | 6003-50 |
| 85880079266004-500TS | GAL- GALAKTÓZA | 6004-500 |
| 85880079266004-50SY | GAL- GALAKTÓZA | 6004-50 |
| 85880079266005-500U5 | GLU - GLUKÓZA | 6005-500 |
| 85880079266005-50T7 | GLU- GLUKÓZA | 6005-50 |
| 85880079266006-500UG | INO-inozitol | 6006-500 |
| 85880079266006-50TE | INO-inozitol | 6006-50 |
| 85880079266007-500UT | LAC-laktóza | 6007-500 |

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| 85880079266007-50TM | LAC-laktóza | 6007-50 |
| 85880079266008-500V6 | MNS-manóza | 6008-500 |
| 85880079266008-50TU | MNS-manóza | 6008-50 |
| 85880079266009-500VH | Melibióza MLB | 6009-500 |
| 85880079266009-50U3 | Melibióza MLB | 6009-50 |
| 85880079266010-500ST | MLT-maltóza | 6010-500 |
| 85880079266010-50SF | MLT-maltóza | 6010-50 |
| 85880079266011-500T6 | MLZ-melesitóza | 6011-500 |
| 85880079266011-50SN | MLZ-melesitóza | 6011-50 |
| 85880079266012-500TH | RAF-rafinózny | 6012-500 |
| 85880079266012-50SV | RAF-rafinózny | 6012-50 |
| 85880079266013-500TU | RHA-ramnóza | 6013-500 |
| 85880079266013-50T4 | RHA-ramnóza | 6013-50 |
| 85880079266014-500U7 | RIB-ribóza | 6014-500 |
| 85880079266014-50TB | RIB-ribóza | 6014-50 |
| 85880079266015-500UJ | SOR-sorbitol | 6015-500 |
| 85880079266015-50TJ | SOR-sorbitol | 6015-50 |
| 85880079266016-500UV | SUC-sacharóza | 6016-500 |
| 85880079266016-50TR | SUC-sacharóza | 6016-50 |
| 85880079266017-500V8 | TRE-trehalóza | 6017-500 |
| 85880079266017-50TY | TRE-trehalóza | 6017-50 |
| 85880079266018-500VK | XYL-xylóza | 6018-500 |
| 85880079266018-50U7 | XYL-xylóza | 6018-50 |
| 85880079266019-500VW | Dusičnany NIT | 6019-500 |
| 85880079266019-50UE | Dusičnany NIT | 6019-50 |
| 85880079266020-500T8 | PEP-peptón | 6020-500 |
| 85880079266020-50SS | PEP-peptón | 6020-50 |
| 85880079266021-500TK | MOČOVINA | 6021-500 |
| 85880079266021-50SZ | MOČOVINA | 6021-50 |
| 85880079266026-500VA | X faktor | 6026-500 |
| 85880079266026-50U4 | X faktor | 6026-50 |
| 85880079266027-500VM | V faktore | 6027-500 |
| 85880079266027-50UB | V faktore | 6027-50 |
| 85880079266028-500VY | Faktor X + V | 6028-500 |
| 85880079266028-50UJ | Faktor X + V | 6028-50 |

Signature: 10.12.2023

DIAGNOSTICS s.r.o.

Petr Sára

COO


