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

ATB /ANM – susceptibility of microorganisms

This is to certify that the *in vitro* diagnostic devices listed below have been assessed for conformity of the product, manufacturing process, technical documentation and quality system with 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 purpose of use as specified by the manufacturer.

For the conformity of the product, the technical documentation has been prepared in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council, Annexes II and III, the procedure for the declaration of conformity has been followed in accordance with Article 17 and Annex IV, and the manufacturer affixes the CE marking to the product in accordance with Annex V. The EU declaration of conformity is issued under the sole responsibility of the manufacturer for the use of the competent authorities, customers and economic entities.

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

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 (EU) of 5 April 2017 on *in vitro* diagnostic medical devices / CSN EN ISO 9001:2016 Quality management system - Requirements / CSN EN ISO 13485:2016 Medical devices - Quality management system / NV No. 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 Performance 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: Terms, definitions and general requirements / ISO 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 / ISO EN ISO 15223- 1:2017 Medical devices - Labelling, marking and information provided with 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	Product code
858800792620083K	NITROCEFIN	2008
858800792630103D	CARBA	3010
85880079266022-500TW	BAC 0,04 - Bacitracin 0,04 j.	6022-500
85880079266022-50T8	BAC 0,04 - Bacitracin 0,04 j.	6022-50
85880079266023-500U9	BAC 10 - Bacitracin 10 j.	6023-500
85880079266023-50TF	BAC 10 - Bacitracin 10 j.	6023-50
85880079266024-500UL	OPT-Optochin	6024-500
85880079266024-50TN	OPT-Optochin	6024-50
85880079266025-500UX	NOV-Novobiocin	6025-500
85880079266025-50TV	NOV-Novobiocin	6025-50
85880079266029-500WB	VK-vancomycin	6029-500
85880079266029-50UR	VK-vancomycin	6029-50
85880079266030-500TM	ITR-itraconazol	6030-500
85880079266030-50T5	ITR-itraconazol	6030-50
85880079266031-500TY	ECO-econazole	6031-500
85880079266031-50TC	ECO-econazole	6031-50
85880079266032-500UB	CLO-clotrimazole	6032-500
85880079266032-50TK	CLO-clotrimazole	6032-50
85880079266033-500UN	FLU-fluconazole	6033-500
85880079266033-50TS	FLU-fluconazole	6033-50
85880079266034-500UZ	AMB-Amfotericín B	6034-500
85880079266034-50TZ	AMB-Amfotericín B	6034-50
85880079266035-500VC	NYS-nystatin	6035-500
85880079266035-50U8	NYS-nystatin	6035-50
85880079266036-500VP	VAN 5µg-vancomycin 5 µg	6036-500
85880079266036-50UF	VAN 5µg-vancomycin 5 µg	6036-50
85880079266037-500W2	BV disk	6037-500
85880079266037-50UN	BV disk	6037-50
85880079266038-500WD	BX disk	6038-500
85880079266038-50UV	BX disk	6038-50
85880079266039-500WQ	BXV disk	6039-500
85880079266039-50V4	BXV disk	6039-50
85880079266040-500U2	NEO-neomycin	6040-500
85880079266040-50TG	NEO-neomycin	6040-50
8588007926700148	MIC GN1	7001
858800792670024A	MIC GN2	7002
858800792670034C	MIC NEF	7003
858800792670044E	MIC GP	7004
858800792670054G	MIC YST	7005
858800792670064J	MIC ENC	7006
858800792680014F	AMK - amikacin	8001
858800792680024H	AMP - ampicilin	8002
858800792680034K	AMS - ampicilin / sulbactam	8003

858800792680044M	AZT - aztreonam	8004
858800792680054P	CAZ - ceftazidime	8005
858800792680064R	CEP - cefepime	8006
858800792680074T	CFZ - cefazolin	8007
858800792680084V	CIP - ciprofloxacin	8008
858800792680094X	CLI - Clindamycin	8009
858800792680104G	CMP - chloramphenicol	8010
858800792680114J	COL - colistin	8011
858800792680124L	CTX- cefotaxim	8012
858800792680134N	CXM- cefuroxime	8013
858800792680144Q	ERT- ertapenem	8014
858800792680154S	ERY- erythromycin	8015
858800792680164U	GEN- gentamycin	8016
858800792680174W	LIZ- linezolid	8017
858800792680184Y	MER-meropenem	8018
8588007926801952	NET-netilmicin	8019
858800792680204K	NFT- nitrofurantoin	8020
858800792680214M	PEN- penicilin	8021
858800792680224P	PIP- piperacilin	8022
858800792680234R	PIT - piperacilin / tazobactam	8023
858800792680244T	T/S- trimetoprim / sulfomethoxazole	8024
858800792680254V	TEC - teicoplanin	8025
858800792680264X	TET- tetracycline	8026
858800792680274Z	TGC- tigecycline	8027
8588007926802853	TOB - Tobramycin	8028
8588007926802955	VAN - Vankomycin	8029

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

10.12.2023