



EC declaration of conformity

Name and address of producer: DIAGNOSTICS Inc.
Hodská 68
924 01 Galanta
Slovakia

The undersigned DIAGNOSTICS Inc. - manufacturer of diagnostic devices, with Company Quality Management System in compliance with standards **ISO 9001:2015** and **ISO 13485:2016** declares, that the following devices:

Diagnostic MD in vitro (IVD)

and inclusion of IVD to group: Other comply with all the essential requirements listed in Annex I of Directive 98/79EC and obligations specified in Annex III, part 2-5 of Directive 98/79EC for In vitro Medical-Diagnostics Devices:

Product name	Product code	SUKL code	Description
GN 24	1001	91459	Identification kit
GP 24	1002	91459	Identification kit
ENC 8	1003	91459	Identification kit
NEISS 8	1004	91459	Identification kit
YST 8	1005	91459	Identification kit
ENT 16	1006	91459	Identification kit
ST 16	1007	91459	Identification kit
Parafínový olej	3001	91461	Diagnostic reagent
IND reagent	3002	91461	Diagnostic reagent
PYR reagent	3003	91461	Diagnostic reagent
VP reagent	3004	91461	Diagnostic reagent
NIT reagent	3005	91461	Diagnostic reagent
HIP reagent	3006	91461	Diagnostic reagent
PHE reagent	3007	91461	Diagnostic reagent
PHS reagent	3008	91461	Diagnostic reagent
DMACA reagent	3009	91461	Diagnostic reagent
CARBA	3010	91459	Diagnostic kit
Alternatívna matrica pre hmotnostnú spektrometriu	3011	94709	Preparation kit
SM – suspenzné médium	4001	91462	Suspension medium
Zn – zinkový prach	5001	91461	Diagnostic reagent
ARA-arabinose	6001-500, 6001-50	91463	Diagnostic discs for microbiology
CEL-cellobiose	6002-500, 6002-50	91463	Diagnostic discs for microbiology
ERY-erythritol	6003-500, 6003-50	91463	Diagnostic discs for microbiology
GAL-galactose	6004-500, 6004-50	91463	Diagnostic discs for microbiology

GLU-glucose	6005-500, 6005-50	91463	Diagnostic discs for microbiology
INO-inositol	6006-500, 6006-50	91463	Diagnostic discs for microbiology
LAC-lactose	6007-500, 6007-50	91463	Diagnostic discs for microbiology
MNS-mannose	6008-500, 6008-50	91463	Diagnostic discs for microbiology
MLB-melibiose	6009-500, 6009-50	91463	Diagnostic discs for microbiology
MLT-maltose	6010-500, 6010-50	91463	Diagnostic discs for microbiology
MLZ-melesitose	6011-500, 6011-50	91463	Diagnostic discs for microbiology
RAF-raffinose	6012-500, 6012-50	91463	Diagnostic discs for microbiology
RHA-rhamnose	6013-500, 6013-50	91463	Diagnostic discs for microbiology
RIB-ribose	6014-500, 6014-50	91463	Diagnostic discs for microbiology
SOR-sorbitol	6015-500, 6015-50	91463	Diagnostic discs for microbiology
SUC-sucrose	6016-500, 6016-50	91463	Diagnostic discs for microbiology
TRE-trehalose	6017-500, 6017-50	91463	Diagnostic discs for microbiology
XYL-xylose	6018-500, 6018-50	91463	Diagnostic discs for microbiology
NIT-nitrates	6019-500, 6019-50	91463	Diagnostic discs for microbiology
PEP-peptone	6020-500, 6020-50	91463	Diagnostic discs for microbiology
URE-urea	6021-500, 6021-50	91463	Diagnostic discs for microbiology
BAC 0,04 - Bacitracin 0,04 u.	6022-500, 6022-50	91463	Diagnostic discs for microbiology
BAC 10 - Bacitracin 10 u.	6023-500, 6023-50	91463	Diagnostic discs for microbiology
OPT-Optochin	6024-500, 6024-50	91463	Diagnostic discs for microbiology
NOV-Novobiocin	6025-500, 6025-50	91463	Diagnostic discs for microbiology
X factor	6026-500, 6026-50	91463	Diagnostic discs for microbiology
V factor	6027-500, 6027-50	91463	Diagnostic discs for microbiology
X+V factor	6028-500, 6028-50	91463	Diagnostic discs for microbiology
VK-vancomycin	6029-500, 6029-50	91463	Diagnostic discs for microbiology
ITR-itraconazol	6030-500, 6030-50	91463	Diagnostic discs for microbiology
ECO-econazole	6031-500, 6031-50	91463	Diagnostic discs for microbiology
CLO-clotrimazole	6032-500, 6032-50	91463	Diagnostic discs for microbiology
FLU-fluconazole	6033-500, 6033-50	91463	Diagnostic discs for microbiology
AMB-amfotericin B	6034-500, 6034-50	91463	Diagnostic discs for microbiology
NYS-nystatin	6035-500, 6035-50	91463	Diagnostic discs for microbiology
VAN 5µg-vancomycin 5 µg	6036-500, 6036-50	91463	Diagnostic discs for microbiology
BV disc	6037-500, 6037-50	91463	Diagnostic discs for microbiology
BX disc	6038-500, 6038-50	91463	Diagnostic discs for microbiology
BXV disc	6039-500, 6039-50	91463	Diagnostic discs for microbiology
NEO	6040-500, 6040-50	91463	Diagnostic discs for microbiology
MIC GN1	7001	96987	MIC kit for Gram negative rods
MIC GN 2	7002	96987	MIC kit for Gram negative rods
MIC NEF	7003	96987	MIC kit for glucose non-fermenting rods
MIC GP	7004	96987	MIC kit for Gram positive rods
MIC YST	7005	96987	MIC kit for yeasts
MIC ENC	7006	96987	MIC kit for enterococci
MIC AMK - amikacín	8001	96987	Diagnostic kit for MIC

MIC AMP - ampicillin	8002	96987	Diagnostic kit for MIC
MIC AMS - ampicillin/sulbactam	8003	96987	Diagnostic kit for MIC
MIC AZT - aztreonam	8004	96987	Diagnostic kit for MIC
MIC CAZ - ceftazidime	8005	96987	Diagnostic kit for MIC
MIC CEP - cefepime	8006	96987	Diagnostic kit for MIC
MIC CFZ - cefazolin	8007	96987	Diagnostic kit for MIC
MIC CIP - ciprofloxacin	8008	96987	Diagnostic kit for MIC
MIC CLI - clindamycin	8009	96987	Diagnostic kit for MIC
MIC CMP - chloramphenicol	8010	96987	Diagnostic kit for MIC
MIC COL - colistin	8011	96987	Diagnostic kit for MIC
MIC CTX - cefotaxime	8012	96987	Diagnostic kit for MIC
MIC CXM - cefuroxime	8013	96987	Diagnostic kit for MIC
MIC ERT - ertapenem	8014	96987	Diagnostic kit for MIC
MIC ERY - erythromycin	8015	96987	Diagnostic kit for MIC
MIC GEN - gentamycin	8016	96987	Diagnostic kit for MIC
MIC LIZ - linezolid	8017	96987	Diagnostic kit for MIC
MIC MER - meropenem	8018	96987	Diagnostic kit for MIC
MIC NET - netilmicin	8019	96987	Diagnostic kit for MIC
MIC NFT - nitrofurantoin	8020	96987	Diagnostic kit for MIC
MIC PEN - penicillin	8021	96987	Diagnostic kit for MIC
MIC PIP - piperacillin	8022	96987	Diagnostic kit for MIC
MIC PIT – piperacillin / tazobactam	8023	96987	Diagnostic kit for MIC
MIC T/S – trimethoprim / sulfamethoxazole	8024	96987	Diagnostic kit for MIC
MIC TEC - teicoplanin	8025	96987	Diagnostic kit for MIC
MIC TET - tetracycline	8026	96987	Diagnostic kit for MIC
MIC TGC - tigecycline	8027	96987	Diagnostic kit for MIC
MIC TOB - tobramycin	8028	96987	Diagnostic kit for MIC
MIC VAN - vancomycin	8029	96987	Diagnostic kit for MIC

Therefore DIAGNOSTICS Inc. declares and assures the following:

1. The a.m. device complies with the applicable provisions of Directive 98/79EC
2. The a.m. device is not included in the list A and B of the Annex II of Directive 98/79EC
3. The manufacturer declares to have established procedure and to maintain it in order to assure the post-marketing surveillance, according to the Directive of 98/79 EC

Certificate of quality management system: Certificate of quality management system no. **M-0200/20** valid until 09.12.2023

All documents, including technical documentation are stored by producer.

This in vitro diagnostic medical device is marked by conformity mark CE.

In Galanta, day 9.12.2020

Mgr. Petr Sára - Managing director

