ITEST plus s.r.o. biological tests, laboratory diagnostics

DECLARATION OF CONFORMITY

for CE – marking according to
EC Directive 98/79 on diagnostic medical devices in vitro

Document number: TF-V.01/9/3/15 ENG

Manufacturer: ITEST plus, s.r.o.

Address: ITEST plus, s.r.o.
Kladská 1032/44c
500 03 Hradec Králové
Česká republika

Product type: **Diagnostic Discs, Carbohydrates Diagnostic Tablets**

Catalogue no.: DD 501; DD 5011; DD 502; DD 5021; DD 503; DD 5031; DD 504; DD 505; DD 506; DD 5061; DD 507; DD 509; DD 511; DD 512; DD 5121; DD 513, DD 5131; DD 514; DD 5141; DD 515;

DT 707, DT 711

SO 341, PP 61

Intended Use:

- The discs are used for fast and simple identification of microbial infectious diseases, based on biochemical characteristics of microbes.

These products are for laboratory use only.

Manufacturer hereby declares under his exclusive responsibility that above listed products are in compliance with applicable Directive of European Parlament no. 98/79/EC for diagnostic medical devices in vitro

safe for intended use under standard conditions.

References:

ČSN EN ISO 13485:2016 ed. 2 Změna A11:2022
ČSN EN ISO 14971:2020 ed. 2 Změna A11:2022
ČSN EN ISO 15223-1: 2022
ČSN EN 13612, opr.1: 2003
ČSN EN ISO 20417: 2021
ČSN EN ISO 14644-1:2019

This Declaration was issued in compliance with Directive of European Parlament no. 98/79/EC for diagnostic medical devices in vitro, as amended.

From 26. 05. 2022 the manufacturer will also meet the requirements of Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices updated on 25. 01. 2022, according to art. 110, paragraphs (3) and (4) temporary provisions which define obligations for manufacturer to fulfill some specific requirements of IVDR 2017/746 as follows:

- **post-market surveillance,**
- **vigilance,**
- **registration of economic operator**

considering that the manufacturer is not allowed to implement any significant changes in design and/or intended use for above listed in vitro diagnostic medical devices after 26. 05. 2022.

Any unauthorised changes to this document, would make this declaration invalid.

Issue date: 03. 07. 2023

Name and Signature: RNDr. Jiří Pospíšil, CSc.,
Executive Chief Officer

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Place of issue: Hradec Králové, Czech republic