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

DECLARATION OF CONFORMITY

for CE – marking according to Annex III par. 3
of Czech Goverment Act No. 56/2015 Coll. and EC Directive 98/79 on diagnostic medical devices in vitro

Document number: TF-V.01/9/1/12 ENG

Manufacturer: ITEST plus, s.r.o.

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

Product type: **Latexaglutination Diagnostic Sets, Other Diagnostic Sets, Diagnostic Sera For Agglutination On Slide**

Catalogue no.: SL 111; SL 112; SL 113; SL 114; SL 115; SL 116; SL 117; SL 118; SL 119; SL 120; SL 141;

SO 331;

PT 102;

AS 401; AS 403; AS 404; AS 405; AS 410

Intended Use:

- The kits are used for fast and straightforward identification of infectious disease-causing microbes. The identification takes advantage of serologic characteristics of the microbes by following a reaction of antigen with latex particle-bound antibody.
- The products are used for identification of infectious disease-causing microbes based on their biochemical and serological characteristics.
- The kits (PT 102) are used as supporting agents during identification of infectious disease-causing microbes.
- The diagnostic sera and antigens are used for identification of individual serologic types of infectious disease-causing microbes. The identification is ascertained either by agglutination reaction on a glass slide or by precipitation in agar.
- These products are for laboratory use only.

Manufacturer hereby declares under his own responsibility that above listed products are in compliance with applicable legistature:

a) Czech Goverment Act No. 56/2015 Coll., on Technical requirements on diagnostic medical devices in vitro, as amended
b) Directive of European Parlament no. 98/79/EC for diagnostic medical devices in vitro
c) Czech Act no. 268/2014 Coll., on Diagnostic medical devices in vitro, and Amendment no. 90/2021 Coll., which changes the Act no. 268/2014 Coll., on medical devices and change of Act no. 634/2004, Coll., and Executive order no. 187/2021 Coll., which changes Executive order 62/2015 Coll., on implemetation of some regulations in Act on medical devices
d) requirements of Annex I of Czech Goverment Act No. 56/2015 Coll., on Technical requirements on diagnostic medical device in vitro,

safe for intended use under standard conditions.

References:

ČSN EN ISO 13485 ed. 2 Změna A11:2022
ČSN EN ISO 14971 ed. 2 Změna A11:2022
ČSN EN ISO 15223-1: 2022
ČSN EN 1041: 2009+A_1: 2014
ČSN EN 13612, opr.1: 2003
ČSN EN ISO 20417: 2021
ČSN EN ISO 14644-1:2019

This Declaration was issued in compliance with Annex III of Czech Goverment Act No. 56/2015 Coll., on Technical requirements on 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: 22. 06. 2022

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

Place of issue: Hradec Králové, Czech republic

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