# Declaration of Conformity for Transport medium for n-CoV 19 modified

In accordance with Directive 98/79/EC of the European Parliament and of the Council whose requirements are taken over by Government Regulation No. 56/2015 Coll., about technical requirements on *in vitro* diagnostic medical devices

Manufacturer: **LabMediaServis s.r.o.**
Address: **Národní 84, 551 01 Jaroměř**

Manufacturer LabMediaServis s.r.o. hereby confirms that the product: Transport medium for n-CoV 19 modified
Trade Mark: **TMCmodif**

Category: In Vitro Diagnostic medical device; abbreviation: IVD
Group: Other IVDs
Intended use: Transport medium for n-CoV 19 modified is intended for transport of samples after the collection of clinical material for the diagnosis of respiratory viruses.

is **in compliance** with:

- Government Regulation No. 56/2015 Coll., as currently in force

The assessment of fundamental characteristics of the product in a specified manner was carried out in accordance with Annex 3 to Government Regulation 56/2015 Coll., about technical requirements for *in vitro* diagnostic medical devices.

The product meets basic requirements of Annex 1 to Government Regulation 56/2015 Coll., which apply to it, and under normal use is safe for its intended purpose.

The manufacturer is responsible for the quality, which is in accordance with the technical documentation and the basic requirements for the product.

Any unauthorized changes to the Declaration of Conformity invalidates this Declaration of Conformity.


Product abbreviation: TMCmodif
Valid from: 18.3. 2020
Version: 1.

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Checked by/Date Ing. Eliška Kalužová /18.3. 2020
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