

Declaration of conformity

*Name and adress
of Manufacturer:* Roboscreen GmbH
Hohmannstrasse 7
04129 Leipzig,
Germany

SRN of Manufacturer: DE-MF-000024661

The **Roboscreen GmbH** declares on own responsibility that the medical device

Name: INSTANT Virus RNA/DNA Kit - FX

Catalogue number: 847-0259200902, 847-0259200903, 847-0259200904

Description: Automated extraction of viral nucleic acids by means of magnetic particles

Basic-UDI-DI: 426238673025921HY

Risk class: Class A

meets all applicable requirements of the Regulation (EU) 2017/746 on in vitro diagnostic medical devices. In the context of conformity with the mentioned regulation the standards referred to in Chapter 4.1 of the Technical Documentation have been fully or partially applied.

*Applied
conformity assessment
procedure:* Annex II (Technical Documentation) and Annex III (Post-market surveillance)

Applied CS: None

*Name and referenc number of
notified body:* Not applicable

*Certificate issued by the
notified body:* Not applicable

Validity (DD.MM.YYYY): 26.05.2023 – 25.05.2024

Place: Leipzig

Date: 26.05.2023

Name and Function: Dr. Ingolf Lachmann, CEO

Legally binding signature:



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CEO
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