

Declaration of conformity

Roboscreen GmbH

Name and adress Hohmannstrasse 7 of Manufacurer: 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 – IPC16

Catalogue number: 847-0259200802

Description: Automated extraction of viral nucleic acids by means of

InnuPure C16 touch

Basic-UDI-DI: 426238673025923J4

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:



Roboscreen GmbH CEO

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