revvity

Manufacturer's name and address
Revvity™ Health Sciences, Inc.
17 P and N Drive
Greenville, SC 29611
USA
SRN: US-MF-000022419

EU Authorized Representative's name and address
Emergo Europe B.V.
Westervoortedijk 60
6827 AT, Arnhem
The Netherlands
SRN: NL-AR-000000116

EU DECLARATION OF CONFORMITY FOR CE-MARKING

Name of the device
Revvity™ 226 Sample Collection Device

Basic UDI-DI: 081258902GR22624

Intended Purpose: Revvity™ 226 Sample Collection Device is intended to be used as a medium to collect and transport blood specimen spots to a laboratory. The sample is to be collected by qualified laboratory professionals.

We, Revvity Health Sciences, Inc., hereby declare that the EU declaration of conformity is issued under the sole responsibility of the manufacturer.

The device(s) mentioned above comply with
Regulation (EU) 2017/746 on in vitro Diagnostic Medical Devices (IVDR).

The product(s) bears the CE mark indicating conformity with the provisions of the regulation and directive(s) mentioned above.

The product(s) are classified as follows:
Class A
in accordance with the Annex VIII, IVDR,
Classification rule 5 (c): specimen receptacles are classified as class A.

Conformity Assessment Procedure:
Annex I & II+III, IVDR

Digitally signed by Moraru Grigore
Date: 2023.08.24 12:50:49 EEST
Reason: MoldSign Signature
Location: Moldova

Date and place of issue
2022-07-31 – Greenville, SC (USA)

Name, position and signature of authorized person

Kerry Chunko

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Sr. Quality Manager

Harmonized Standards, Common Specifications and other standards used for conformity assessment of compliance

EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971	Medical devices - Application of risk management to medical devices
EN ISO 18113-1	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
CLSI NBS01-A6	Blood Collection of Filter Paper for Newborn Screening