CENTOGENE
THE RARE DISEASE COMPANY

Declaration of Conformity

DoC-ID: TD-0002
Revision: 3.0

Manufacturer:	CENTOGENE GmbH Am Strande 7 18055 Rostock, Germany
SRN: (Single Registration Number acc. to Art. 28, IVDR (EU) 2017/746)	DE-MF-000020652
In Vitro Diagnostic Medical Device:	CentoCard®
Intended Purpose:	The CentoCard® is a specimen receptacle intended to be used as a medium to collect and transport dried whole blood specimen spots to a laboratory to enable genetic and biochemical testing.
Basic UDI-DI:	4260433590000018K
Medical Device Nomenclature (EMDN): (acc. to IVDR (EU) 2017/746, Art. 23)	W0501010199, Venous or Arterious Blood Collection Devices – Other W0501010299, Capillary Blood Collection Devices – Other
GMDN preferred term:	Dried blood spot collection card IVD
GMDN primary code:	66256
Product Classification (acc. to IVDR (EU) 2017/746, Annex VIII)	Class: A Rule(s): 5
Applicable Union legislation(s):	Regulation (EU) 2017/746 (IVDR)
Notified Body: (Name, address, ID)	N/A (Class A device)

CENTOGENE GmbH, ensures and declares in sole responsibility the conformity of the above-mentioned *in vitro* diagnostic medical device(s) according to the Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (and the Union legislation(s) specified above that provides for the issuing of an EU declaration of conformity).

CENTOGENE GmbH ensures and declares that the obligations imposed by Regulation (EU) 2017/746 are fulfilled and that the above-mentioned *in vitro* diagnostic medical device(s) meets the General Safety and Performance Requirements of Annex I, Regulation (EU) 2017/746.

The respective certificate is valid until 2026-05-02.

The applied standards and if applicable common specifications for the above-mentioned *in vitro* diagnostic medical device(s) are listed in the respective Technical Documentation.

Rostock, 03 May 2023

Location, date

Person Responsible for Regulatory Compliance