NexusDx

CE Declaration of Conformity

EU Directive to which Conformity is declared: Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices.
Conformity Assessment Procedure: General IVD Annex III

Referenced Standards:

BS EN ISO 14971:2019	BS EN ISO 18113-1:2011	BS EN 13612:2002
BS EN ISO 23640:2015	BS EN ISO 18113-2:2011	BS EN ISO 15223-1:2016
BS EN 13975:2003	BS EN ISO 18113-3:2011	ISO 13485:2016

Manufacturer:	**European Authorized Representative:**
Nexus Dx, Inc. 6759 Mesa Ridge Road San Diego, CA 92121 USA Tel: 858-410-4600 Fax: 858-410-4700	TheraGenesis GmbH Bahnhofstrasse 5 55276 Oppenheim Germany Tel: +49 (0) 151 506 403 14

Device	Part Number	Declaration Date
IB10 sphingotest® Troponin-99	IVR-IB50	March 1, 2019
IB10 sphingotest® 3-in-1 Cardiac	IVR-IB51	March 1, 2019
IB10 sphingotest® D-Dimer	IVR-IB52	March 1, 2019
IB10 sphingotest® SOB	IVR-IB53	March 1, 2019
IB10 sphingotest® beta-hCG	IVR-IB54	March 1, 2019
IB10 sphingotest® TSH	IVR-IB55	March 1, 2019
IB10 sphingotest® NT-proBNP	IVR-IB56	January 30, 2019
IB10 sphingotest® DPP3	IVR-IB58	August 29, 2019
IB10 sphingotest® penKid®	IVR-IB62	December 19, 2019
IB10 sphingotest® PCT	IVR-IB65	March 5, 2020
IB10 sphingotest® bio-ADM®	IVR-IB61	May 29, 2020

The undersigned, declares that the devices listed above conform to the standards as described above including the essential requirements of Annex I. CE Marking will be affixed per Article 16.

DATE: May 29, 2020

PLACE: San Diego, California, USA

Dustin Tano, Sr. VP of Operations

NEXUS DX, INC. CORPORATE SEAL JUNE 29, 2009 DELAWARE

Nexus Dx, Inc.
6759 Mesa Ridge Road
San Diego, CA 92121
Tel: 858-410-4600
Fax: 858-410-4700

EU Declaration of Conformity

Manufacturers Name:	Nexus Dx, Inc
Manufacturers Address:	6759 Mesa Ridge Road San Diego, CA 92121 USA
SRN (Single Registration Number):	TBD
Authorized Representative Name:	TheraGenesis GmbH
Authorized Representative Address:	Bahnhofstrasse 5, D-55276 Oppenheim, Germany Tel: + 49 (0) 151 506 403 14 erik.hesse@theragenesis.com
Basic UDI-DI:	0857376006IVR-IB59X7
Classification:	Class A
Conformity assessment procedure:	Annex II Annex III
Notified Body Name:	Not Applicable
Notified Body Identification Number:	Not Applicable
IVDR Certificate Number:	Not Applicable
Device: Nexus IB10 Analyzer	**Catalog Number:** 050-00077
The intended purpose:	The Nexus IB10 analyzer is an automated in-vitro immunology analyzer that quantitatively measures antigens or antibodies in whole blood or plasma samples on a dedicated disc, in a near patient or laboratory setting. Utilizing an immunochromatographic assay (ICA) method, the Nexus IB10 measures and analyzes results with a bult-in sensor.
Common Specifications (if applicable):	Not Applicable

This declaration of conformity is issued under the sole responsibility of Nexus Dx, Inc. We hereby declare that these medical device(s) specified above meet the provision of the Regulation (EU) IVDR 2017/746 for medical devices. This declaration is supported by the Quality System certification to ISO 13485:2016 issued by BSI.

Signed on behalf of Nexus Dx, a legal manufacturer.

DATE: 2022-08-22

PLACE: San Diego, California, USA

VP OF OPERATIONS

Responsible Person/Title

NEXUS DX, INC CORPORATE SEAL JUNE 29, 2009 DELAWARE

EU Declaration of Conformity

Manufacturers Name:	Nexus Dx, Inc
Manufacturers Address:	6759 Mesa Ridge Road San Diego, CA 92121 USA
SRN (Single Registration Number):	TBD
Authorized Representative Name:	TheraGenesis GmbH
Authorized Representative Address:	Bahnhofstrasse 5, D-55276 Oppenheim, Germany Tel: + 49 (0) 151 506 403 14 erik.hesse@theragenesis.com
Basic UDI-DI:	0857376006IVR-IB60WQ
Classification:	Class A
Conformity assessment procedure:	Annex II Annex III
Notified Body Name:	Not Applicable
Notified Body Identification Number:	Not Applicable
IVDR Certificate Number:	Not Applicable
Device: Nexus IB10 EQC, Disc	**Catalog Number:** 050-00078
The intended purpose:	The Nexus IB10 EQC is for testing performance check of the Nexus IB10 system.
Common Specifications (if applicable):	Not Applicable

This declaration of conformity is issued under the sole responsibility of Nexus Dx, Inc. We hereby declare that these medical device(s) specified above meet the provision of the Regulation (EU) IVDR 2017/746 for medical devices. This declaration is supported by the Quality System certification to ISO 13485:2016 issued by BSI.

Signed on behalf of Nexus Dx, a legal manufacturer.

DATE: 2022-08-22 **PLACE: San Diego, California, USA**

VP OF OPERATIONS
Responsible Person/Title

NEXUS DX, INC. CORPORATE SEAL JUNE 29, 2009 DELAWARE