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

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:

EN ISO 15223-1:2016	EN ISO 13485:2016	EN 13612:2002
EN ISO 14971:2012	EN ISO 18113-1:2011	EN ISO 18113-3:2011
EN 61010-2-101:2002	EN 61010-2-010:2003	IEC 61010-2-081:2002; A1
EN 61326-2-6:2006	EN 62304:2006	EN 62366:2008
EN60601-1-2:2007	EN 60601-1:2006	

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
Nexus IB10	IVR-IB59	March 20, 2019
Nexus IB10 EQC	IVR-IB60	July 31, 2019

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: January, 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