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 14971:2012	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	
Samsung LABGEO^{IB} Troponin I Test	IVR-IB05	June 29, 2012	Original Declaration
IB10 sphingotest® Troponin-99	IVR-IB50	March 1, 2019	Rebranded Product
Note: On or prior to January 1, 2020, the product (IVR-IB50) will be made available in EU/EFTA. The product originally declared (IVR-IB05) will be discontinued as supplies are exhausted.			

Device	Part Number	Declaration Date	
Samsung LABGEO^{IB} CHF Test NT-proBNP	IVR-IB06	June 29, 2012	Original Declaration
Note: As of about January 1, 2020, the product (IVR-IB06) will be discontinued as supplies are exhausted.			

Device	Part Number	Declaration Date	
IB10 sphingotest® NT-proBNP	IVR-IB56	January 30, 2019	New Product
Note: Prior to January 1, 2020, the product (IVR-IB56) will replace IVR-IB06 and be made available in EU/EFT.			

Device	Part Number	Declaration Date	
Samsung LABGEO^{IB} Cardiac 3-in-1 Panel Test Troponin I/CK-MB/Myoglobin	IVR-IB08	July 16, 2012	Original Declaration
IB10 sphingotest® 3-in-1 Cardiac	IVR-IB51	March 1, 2019	Rebranded Product
Note: On or prior to January 1, 2020, the product (IVR-IB51) will be made available in EU/EFTA. The product originally declared (IVR-IB08) will be discontinued as supplies are exhausted.			

Device	Part Number	Declaration Date	
Samsung LABGEO^{IB} CHF Plus Test NT-proBNP/Troponin I	IVR-IB07	October 31, 2012	Original Declaration
Note: As of about January 1, 2020, the product (IVR-IB07) will be discontinued as supplies are exhausted.			

NexusDx

Device	Part Number	Declaration Date	
Samsung LABGEO[IB] D-Dimer Test	IVR-IB09	December 19, 2012	Original Declaration
IB10 sphingotest® D-Dimer	IVR-IB52	March 1, 2019	Rebranded Product
Note: On or prior to January 1, 2020, the product (IVR-IB52) will be made available in EU/EFTA. The product originally declared (IVR-IB09) will be discontinued as supplies are exhausted.			

Device	Part Number	Declaration Date	
Samsung LABGEO[IB] SOB Cardiac 3 Panel Test Troponin I/ NT-proBNP/ D-Dimer	IVR-IB11	June 25, 2013	Original Declaration
IB10 sphingotest® SOB	IVR-IB53	March 1, 2019	Rebranded Product
Note: On or prior to January 1, 2020, the product (IVR-IB53) will be made available in EU/EFTA. The product originally declared (IVR-IB11) will be discontinued as supplies are exhausted.			

Device	Part Number	Declaration Date	
Samsung LABGEO[IB] beta-hCG Test	IVR-IB12	February 21, 2014	Original Declaration
IB10 sphingotest® beta-hCG	IVR-IB54	March 1, 2019	Rebranded Product
Note: On or prior to January 1, 2020, the product (IVR-IB54) will be made available in EU/EFTA. The product originally declared (IVR-IB12) will be discontinued as supplies are exhausted.			

Device	Part Number	Declaration Date	
Samsung LABGEO[IB] TSH Test	IVR-IB15	November 25, 2014	Original Declaration
IB10 sphingotest® TSH	IVR-IB55	March 1, 2019	Rebranded Product
Note: On or prior to January 1, 2020, the product (IVR-IB55) will be made available in EU/EFTA. The product originally declared (IVR-IB15) will be discontinued as supplies are exhausted.			

Device	Part Number	Declaration Date	
Samsung IB B·R·A·H·M·S PCT	IVR-IB18	December 18, 2015	Original Declaration
Note: As of about January 1, 2020, the product (IVR-IB18) will be discontinued as supplies are exhausted.			

Device	Part Number	Declaration Date	
Samsung IB B·R·A·H·M·S PCT & MR-proADM	IVR-IB22	April 20, 2017	Original Declaration
Note: As of about January 1, 2020, the product (IVR-IB22) will be discontinued as supplies are exhausted.			

Device	Part Number	Declaration Date	
IB10 sphingotest® DPP3	IVR-IB58	August 29, 2019	Original Declaration

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: August 29, 2019

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	
Samsung LABGEO^{IB} EQC	IVR-IB99	November 8, 2018	Original Declaration
Nexus IB10 EQC	IVR-IB60	July 31, 2019	Rebranded Product
Note: On or prior to January 1, 2020, the product (IVR-IB60) will be made available in EU/EFT. The product originally declared (IVR-IB99) will be discontinued as supplies are exhausted.			

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: July 31, 2019

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

List of Devices	Part Numbers	Declaration Date
Samsung LABGEO^{IB} EQC	IVR-IB99	November 8, 2018
Nexus IB10	IVR-IB59	March 20, 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: March 20, 2019 **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