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 15223-1:2021
BS EN 13975:2003	BS EN ISO 18113-3:2011	ISO 13485:2016

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

Current Brand:

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

Rebranded:

Device	Part Number	Declaration Date
IB10 DPP3	IVR-IB58A	August 29, 2019

Note: On or prior to January 1, 2024, the rebranded product will be made available in EU/EFTA and countries where CE mark is applicable. The product originally declared with sphingotest trademark will be discontinued.

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: Jan 1st, 2024

PLACE: San Diego, California, USA

Nam Shin, President

NEXUS DX, INC CORPORATE SEAL 2009 DELAWARE

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