

CERTIFICATE

Number: 3902782

The management system of the organization(s) and locations mentioned on the addendum belonging to:

S.D. Sight Diagnostics Ltd.

23 Menachem Begin Rd.
Tel Aviv 6618356
Israel

Manufacturer Facility Identifier F005231

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA N. 16/2013, 23/2012 and 67/2009
Canada: Medical Devices Regulations - Part 1- SOR 98/282
Japan: MHLW Ministerial Ordinance 169 and Article 4 to Article 68
United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

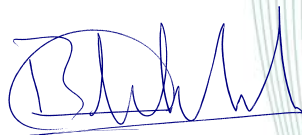
Scope:

Design, development, manufacture, distribution, installation and service of in-vitro diagnostic hematological analyzers, test kits and control materials for laboratory, healthcare facility and point of care use

Certificate expiry date: 2024-02-01
Certificate effective date: 2021-02-09
Certified since: 2021-02-09

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



A.A.P.M. van Vught
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
<https://www.dekra-product-safety.com/en/certified-organizations>

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.



ADDENDUM

To certificate: 3902782

The management system of the organization(s) and/or location(s) of:

S.D. Sight Diagnostics Ltd.

**23 Menachem Begin Rd.
Tel Aviv 6618356
Israel**

Certified organization(s) and/or locations:

Different scope

S.D. Sight Diagnostics Ltd.
48 Menachem Begin Rd.
Tel Aviv 6618004

Manufacturing of testing kits for in-vitro diagnostic hematological analyzers

Addendum expiry date: 2024-02-01
Addendum effective date: 2021-02-09