Annex to declaration of accreditation (scope of accreditation)
Normative document: EN ISO/IEC 17021-1:2015
Registration number: **C 096**

of **The Standards Institution of Israel**
**Quality and Certification Division**

This annex is valid from: **22-10-2020** to **01-09-2024** Replaces annex dated: **16-10-2019**

**Prolonged till 01-12-2024**

## Location(s) where activities are performed under accreditation

### Head Office

42 Chaim Levanon Street
69977
Tel Aviv
Israel

| Standard / Normative document | Certification scheme [1] |
|---|---|
| ISO 9001 | Quality management system for the scopes<br>(reference to IAF-codes and NACE Rev. 2 where relevant) :<br><br>1 agriculture, forestry and fishing<br>3 food products, beverages and tobacco<br>4 textiles and textile products<br>7 pulp, paper and paper products<br>8 publishing companies<br>9 printing companies<br>10 manufacture of coke and refined petroleum products<br>12 chemicals, chemical products and fibres<br>13 pharmaceuticals<br>14 rubber and plastic products<br>15 non-metallic mineral products<br>16 concrete, cement, lime, plaster, etc.<br>17 basic metals and fabricated metal products<br>18 machinery and equipment<br>19 electrical and optical equipment<br>21 aerospace<br>22 other transport equipment<br>24 recycling<br>25 electricity supply<br>27 water supply<br>28 construction<br>29 wholesale and retail trade; repair of motor vehicles, motorcycles and |

[1] If there is a referral to a scope (Sxxx), this constitutes a scheme of an accepted scheme owner. The accepted version is mentioned on the concerning scope of the scheme owner..

This annex has been approved by the Board of the Dutch Accreditation Council, on its behalf,

J.A.W.M. de Haas

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|---|---|
| | personal and household goods |
| | 31 transport, storage and communication<br>33 information technology<br>34 engineering services<br>35 other services<br>36 public administration<br>38 health and social work |
| ISO 13485 | Medical Devices - Quality Management Systems - Requirements for regulatory purposes for the scopes:<br>- 1.1 Non-active Medical Devices<br>○ General non-active, non-implantable medical devices<br>○ Non-active implants<br>○ Devices for wound care<br>○ Non-active dental devices and accessories<br>○ Non-active medical devices other than specified above<br>- 1.2 Active (non-implantable) Medical Devices<br>○ General active medical devices<br>○ Devices for imaging<br>○ Monitoring devices<br>○ Devices for radiation therapy and thermotherapy<br>○ Active (non-implantable) medical devices other than specified above<br>- 1.4 In Vitro Diagnostic Medical Devices<br>○ Reagents and reagent products, calibrators and control materials for :<br>Clinical Chemistry<br>Immunochemistry (Immunology)<br>Haemotology/Haemostasis/Immunohematology<br>Microbiology<br>Infectious Immunology<br>Histology/Cytology<br>Genetic Testing<br>○ In Vitro Diagnostic Instruments and software<br>- 1.5 Sterilization Methods for Medical Devices<br>○ Ethylene oxide gas sterilization (EOG)<br>- 1.7 Parts and Services<br>- Raw materials<br>- Components<br>- Subassemblies<br>- Calibration services*<br>- Distribution services<br>- Maintenance services<br>- Transportation services<br>- Other services<br>*organizations providing calibration services should be accredited to ISO/IEC 17025 |
| ISO 14001 | Environmental management system certification according to ISO 14001, for the scopes:<br>(reference to IAF-codes and NACE rev. 2 where relevant) |

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