

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 **01-09-20284**

Replaces annex dated: **16-09-2019**

**Prolonged until 01-05-2025**

**Imposed suspension for the crossed out activities as of 03-02-2025**

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

**Head Office**

42 Chaim Levanon Street  
69977  
Tel Aviv  
Israel

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

<sup>1</sup> 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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Standard / Normative document	Certification scheme <sup>1</sup>
	28 construction 29 wholesale and retail trade; repair of motor vehicles, motorcycles and personal and household goods
	31 transport, storage and communication 33 information technology 34 engineering services 35 other services 36 public administration 38 health and social work
ISO 13485	<p><del>Medical Devices – Quality Management Systems – Requirements for regulatory purposes for the scopes:</del></p> <ul style="list-style-type: none"> <li><del>— 1.1 Non-active Medical Devices</del> <ul style="list-style-type: none"> <li><del>○ General non-active, non-implantable medical devices</del></li> <li><del>○ Non-active implants</del></li> <li><del>○ Devices for wound care</del></li> <li><del>○ Non-active dental devices and accessories</del></li> <li><del>○ Non-active medical devices other than specified above</del></li> </ul> </li> <li><del>— 1.2 Active (non-implantable) Medical Devices</del> <ul style="list-style-type: none"> <li><del>○ General active medical devices</del></li> <li><del>○ Devices for imaging</del></li> <li><del>○ Monitoring devices</del></li> <li><del>○ Devices for radiation therapy and thermotherapy</del></li> <li><del>○ Active (non-implantable) medical devices other than specified above</del></li> </ul> </li> <li><del>— 1.4 In Vitro Diagnostic Medical Devices</del> <ul style="list-style-type: none"> <li><del>○ Reagents and reagent products, calibrators and control materials for:</del> <ul style="list-style-type: none"> <li><del>Clinical Chemistry</del></li> <li><del>Immunochemistry (Immunology)</del></li> <li><del>Haematology/Haemostasis/Immunohematology</del></li> <li><del>Microbiology</del></li> <li><del>Infectious Immunology</del></li> <li><del>Histology/Cytology</del></li> <li><del>Genetic Testing</del></li> </ul> </li> <li><del>○ In Vitro Diagnostic Instruments and software</del></li> </ul> </li> <li><del>— 1.5 Sterilization Methods for Medical Devices</del> <ul style="list-style-type: none"> <li><del>○ Ethylene oxide gas sterilization (EOG)</del></li> </ul> </li> <li><del>— 1.7 Parts and Services</del> <ul style="list-style-type: none"> <li><del>— Raw materials</del></li> <li><del>— Components</del></li> <li><del>— Subassemblies</del></li> <li><del>— Calibration services*</del></li> <li><del>— Distribution services</del></li> <li><del>— Maintenance services</del></li> <li><del>— Transportation services</del></li> <li><del>— Other services</del></li> </ul> </li> </ul> <p><del>*organizations providing calibration services should be accredited to ISO/IEC 17025</del></p>
ISO 14001	<p>Environmental management system certification according to ISO 14001, for the scopes: (reference to IAF-codes and NACE rev. 2 where relevant)</p>

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	13 pharmaceuticals
	14 rubber and plastic products
	16 concrete, cement, lime, plaster, etc.
	17 basic metals and fabricated metal products
	18 machinery and equipment
	19 electrical and optical equipment
	21 aerospace
	22 other transport equipment
	23 manufacturing not elsewhere classified
	24 recycling
	25 electricity supply
	27 water supply
	28 construction
	29 wholesale and retail trade, repair of motor vehicles, motorcycles and personal and household goods
	31 transport, storage and communication
	33 information technology
	34 engineering services
	35 other services
	36 public administration
	38 health and social work