Annex to declaration of accreditation (scope of accreditation)
Normative document: EN ISO/IEC 17021-1:2015
Registration number: **C 589**

of **DEKRA Certification B.V.**
Product Testing & Certification

This annex is valid from: **26-11-2025** to **01-03-2027** Replaces annex dated: **25-05-2023**

Location(s) where activities are performed under accreditation

Head Office

Meander 1051
6802 ED
Arnhem
The Netherlands

Location	Certification Scheme
Meander 1051 6802 ED Arnhem The Netherlands	ISO 9001 ISO 13485 EN ISO 13485
1945 The Exchange SE #300 Atlanta, GA 30339 United States of America	ISO 9001 ISO 13485 EN ISO 13485
PO box 771, Shoham Israel	ISO 9001 ISO 13485 EN ISO 13485
K.K., West Wing 7F, 1-28-10 Akebono-Cho, Tachikawa-shi, Tokyo, Japan	ISO 9001 ISO 13485 EN ISO 13485
5F, No. 250, Jiangchangsan Road, Shanghai, 200436, P. R. China	ISO 9001 ISO 13485 EN ISO 13485

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 [1]
ISO 9001	Quality management system for the scopes: (reference to IAF-codes and NACE Rev. 2 where relevant) 12 chemicals, chemical products and fibres 14 rubber and plastic products 17 basic metals and fabricated metal products 18 machinery and equipment 19 electrical and optical equipment 29 wholesale and retail trade, repair of motor vehicles, motorcycles and personal and household goods 34 engineering services
ISO 13485	Medical devices — Quality management systems — Requirements for regulatory purposes for the scopes: 1.1 - Non-active medical devices - General non-active, non-implantable medical devices - Non-active implants - Devices for wound care - Non-active dental devices and accessories - Non-active medical devices other than specified above 1.2 - Active (non-implantable) medical devices - General active medical devices - Devices for imaging - Monitoring devices - Devices for radiation therapy and thermotherapy - Active (non-implantable) medical devices other than specified above 1.3 - Active implantable medical devices - General active implantable medical devices - Implantable medical devices other than specified above 1.4 - In Vitro Diagnostic Medical Devices - Reagents and reagent products, calibrators and control materials for: Clinical Chemistry Immunochemistry (Immunology) Haemotology/Haemostasis/Immunohematology Microbiology Infectious Immunology Histology/Cytology Genetic Testing - In Vitro Diagnostic Instruments and software - IVD Medical Devices other than specified above 1.5 - Sterilization Methods for Medical Devices - Ethylene oxide gas sterilization (EOG)- including applicable quality management system requirements within ISO 11135

[1] If no date or version number is mentioned for a normative document, the accreditation concerns the most current version of the document or scheme.
[1] If there is a reference to a code starting with NAW, NAP, EA or IAF, this concerns a scheme mentioned on the RvA-BR010-lijst.

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Standard / Normative document	Certification scheme [1]
	- Moist heat - including applicable quality management system requirements within ISO 17665-1 - Aseptic processing - Radiation sterilization (e.g. gamma, x-ray, electron beam) - including applicable quality management system requirements within ISO 11137-1 -Low temperature steam and formaldehyde sterilization -Thermic sterilization with dry heat -Sterilization with hydrogen peroxide -Sterilization method other than specified above 1.6 - Devices incorporating/utilizing specific substances/technologies - Medical devices incorporating medicinal substances - Medical devices utilizing tissues of animal origin - Medical devices incorporating derivates of human blood - Medical devices utilizing micromechanics - Medical devices utilizing nanomaterials - Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed 1.7 - Parts and Services - Raw materials - Components - Subassemblies - Calibrations services* - Distribution services - Maintenance services - Transportation services - Other services *organizations providing calibration services should be accredited to ISO/IEC 17025