Bijlage bij accreditatieverklaring (scope van accreditatie)
Normatief document: EN ISO/IEC 17021-1:2015
Registratienummer: **C 589**

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

Deze bijlage is geldig van: **25-05-2023** tot **01-03-2027** Vervangt bijlage d.d.: **18-04-2023**

Locatie(s) waar activiteiten onder accreditatie worden uitgevoerd

Hoofdkantoor

Meander 1051
6802 ED
Arnhem
Nederland

Locatie	Certificatie Schema
Meander 1051 6802 ED Arnhem Nederland	ISO 9001 ISO 13485
1850 Gateway Blvd – Suite 925 Concord, CA, 94520 USA (West)	ISO 9001 ISO 13485 EN ISO 13485
Tzur 8. 4486200 Tzur Yigal Israël	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

Deze bijlage is goedgekeurd door het bestuur van de Raad voor Accreditatie, namens deze,

mr. J.A.W.M. de Haas

Bijlage bij accreditatieverklaring (scope van accreditatie)
Normatief document: EN ISO/IEC 17021-1:2015
Registratienummer: **C 589**

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

Deze bijlage is geldig van: **25-05-2023** tot **01-03-2027** Vervangt bijlage d.d.: **18-04-2023**

Norm / Normatief document	**Certificatieschema[1]**
ISO 9001	Kwaliteitssysteemcertificatie, voor de werkterreinen: (verwijzing naar IAF codes en NACE rev. 2 waar van toepassing): 12 chemische industrie 14 rubber en kunststoffen 17 metaalindustrie 18 machines, apparaten en werktuigen 19 elektrische en optische apparaten en instrumenten 29 groot- en kleinhandel, reparatie van auto's, motorrijwielen en huishoudelijke artikelen 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 - Moist heat - including applicable quality management system requirements within ISO 17665-1

[1] Indien geen datum of versienummer is vermeld betreft de accreditatie de actuele versie van het document of schema.
[1] Indien wordt verwezen naar een codering beginnende met NAW, NAP, EA of IAF dan betreft het een schema opgenomen in de RvA-BR010 lijst.

Norm / Normatief document	Certificatieschema[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