Annex to declaration of accreditation (scope of accreditation)
Normative document: EN ISO/IEC 17021-1:2015
Registration number: **C 122**

of **BSI Group The Netherlands**

This annex is valid from: **29-11-2023** to **01-06-2025** Replaces annex dated: **03-05-2023**

Location(s) where activities are performed under accreditation

Head Office

John M. Keynesplein 9
1066 EP
Amsterdam
The Netherlands

Location	Certification Scheme
John M. Keynesplein 9 1066 EP Amsterdam The Netherlands	ISO 9001 SHE Checklist Contractors (VCA) ISO 27001 ISO 13485 ISO 14001 Directive 2014/68/EU NEN 7510-1 AQAP 2110
Kitemark Court Davy Avenue Knowlhill, Milton Keynes, MK5 8PP United Kingdom	ISO 13485 Directive 2014/68/EU
Al. "Solidarności" 171 00-877 Warsaw Poland	ISO 9001 SHE Checklist Contractors (VCA) ISO 27001 ISO 14001
Ocean Gate Minato Mirai 3F, 3-7-1 Minatomirai, Nishi-ku, Yokohama, Kanagawa, 220-0012 Japan	ISO 13485
12950 Worldgate Drive, Suite 800 Herndon, VA 20170-6007 United States of America	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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Location	Certification Scheme
Suite 29.01, Level 29 The Gardens North Tower Mid Valley City, Lingkaran Syed Putra Kuala Lumpur Wilayah Persekutuan 59200 Malaysia	ISO 13485
518B, Dien Bien Phu Street Ward 21 Binh Thanh District Ho Chi Minh City Vietnam	ISO 13485

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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) 3 food products, beverages and tobacco 4 textiles and textile products 9 printing companies 12 chemicals, chemical products and fibres 14 rubber and plastic products 17 basic metals and fabricated metal products 18 machinery and equipment 28 construction 29 wholesale and retail trade; repair of motor vehicles, motorcycles and personal and household goods 30 hotels and restaurants 31 transport, storage and communication 32 financial intermediation; real estate; renting 33 information technology 35 other services 36 public administration 37 education 38 health and social work 39 other social services
AQAP 2110	Nato Quality Assurance requirements for design, development and production
SHE Checklist Contractors (VCA)	The certification of the safety, health and environmental management system for contractors: (reference to IAF-codes and NACE Rev. 2 where relevant) *(NAP-0202)*
NEN 7510-1 Medische informatica – Informatiebeveiliging in de zorg	NCS 7510 Conformiteitsbeoordeling – Eisen aan instellingen die audits ten behoeve van certificatie van informatiebeveiligingsmanagementsystemen in de zorg uitvoeren Voor de clusters Z en B: - Zorginstellingen - Beheerders van persoonlijke gezondheidsinformatie, anders dan zorginstellingen *(NAP-0210)*
ISO/IEC 27001:2013 *Geldig tot 01-11-2025*	Information Security Management Systems Accreditation granted in accordance with ISO/IEC 27006
ISO/IEC 27001:2022	Information Security Management Systems Accreditation granted in accordance with ISO/IEC 27006
ISO 13485	Medical Devices - Quality Management Systems - Requirements for regulatory purposes for the scopes: - 1.1 Non-active medical devices

[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.

Standard / Normative document	Certification scheme [1]
	- 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 (IVD) - 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 - Aseptic processing - including applicable quality management system requirements within ISO 13408-1 - 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 - including applicable quality management system requirements within ISO 25424 - Thermic sterilization with dry heat - including applicable quality management system requirements within ISO 20857 - Sterilization with hydrogen peroxide - Sterilization method other than specified above - including applicable quality management system requirements within ISO 14937 - 1.6 Devices incorporating/utilizing specific substances/technologies - Medical devices incorporating medicinal substances - Medical devices utilizing tissues of animal origin

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Standard / Normative document	Certification scheme [1]
	- 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 - Medical devices incorporating or utilizing specific substances/technologies/elements,other than specified above - 1.7 Parts and Services - Raw materials - Components - Subassemblies - Calibration services * - Distribution services - Maintenance services - Transportation services - Other services (*) Organizations providing calibration services should be accredited to ISO/IEC 17025
ISO 14001	Environmental management system certification according to ISO 14001, for the scopes: Certification scheme for environmental management systems according to ISO 14001, for the scopes: *(NAP-0028)* (reference to IAF-codes and NACE rev. 2 where relevant) 2 mining and quarrying 3 food products, beverages and tobacco 4 textiles and textile products 6 wood and wood products 7 pulp, paper and paper products 9 printing companies *(limited to NACE section C 18.1)* 10 manufacture of coke and refined petroleum products 12 chemicals, chemical products and fibres 13 pharmaceuticals 14 rubber and plastic products 17 basic metals and fabricated metal products *(limited to NACE section C24, minus 24.46 and section C 25)* 18 machinery and equipment *(limited to NACE section C 28)* 19 electrical and optical equipment 21 aerospace 22 other transport equipment 24 recycling 27 water supply 28 construction 29 wholesale and retail trade, repair of motor vehicles, motorcycles and personal and household goods 30 hotels and restaurants 31 transport, storage and communication *(limited to NACE section H 49-52)* 32 financial intermediation; real estate; renting *(limited to NACE section L)* 33 information technology 34 engineering services

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Standard / Normative document	Certification scheme [1]
	35 other services *(limited to NACE section M 69, 70, 73, 74.3, 74.9, 75)* 36 public administration 37 education 38 health and social work 39 other social services *(except NACE section J 59, S94)*

Product / Product Group	Module / article	Conformity assessment procedure
Directive 2014/68/EU **Pressure equipment** *The accreditation for the specified activities is suitable for notification*		
Pressure equipment and assemblies	Conformity based on full quality assurance(module H)	Annex III, module H