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: **11-12-2019** to **01-03-2023** Replaces annex dated: **21-02-2019**

Location(s) where activities are performed under accreditation

Head Office

Meander 1051
6802 ED
Arnhem
The Netherlands

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

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

J.A.W.M. de Haas
Director of Operations

[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 list (https://www.rva.nl/en/document/download/BR010-lijst).

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Standard / Normative document	**Certification scheme** [1]

ISO 13485
EN ISO 13485
	Medical Devices - Quality Management Systems - Requirements for regulatory purposes for the scopes:
	- 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
	- 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
	- Active implantable medical devices
	  - General active implantable medical devices
	  - Implantable medical devices other than specified above
	- 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
	- Sterilization Methods for Medical Devices
	  - Ethylene oxide gas sterilization (EOG)
	  - Moist heat
	  - Aseptic processing
	  - Radiation sterilization (e.g. gamma, x-ray, electron beam)
	  - Sterilization method other than specified above
	- 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

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Product / Product Group	Module / article	Conformity assessment procedure
Directive 2014/34/EU **Equipment and protective systems intend for use in potentially explosive atmospheres** *The accreditation for the specified activities is suitable for notification*		
Equipment category M 1 of equipment-group I– [electrical equipment] [and] [non-electrical equipment]	Conformity to type based on quality assurance of the production process (module D)	Annex IV
Equipment category 1 of equipment-group II, explosive atmosphere due to gases, vapours or mists – [electrical equipment] [and] [non-electrical equipment]	Conformity to type based on quality assurance of the production process (module D)	Annex IV
Equipment category 1 of equipment-group II, explosive atmosphere due to air/dust mixtures – [electrical equipment] [and] [non-electrical equipment]	Conformity to type based on quality assurance of the production process (module D)	Annex IV
Equipment category M2 of equipment-group I – [electrical equipment] [and] [non-electrical equipment]	Conformity to type based on product quality assurance (module E)	Annex VII
Equipment category 2 of equipment-group II, explosive atmosphere due to air/dust mixture – [electrical equipment]	Conformity to type based on product quality assurance (module E)	Annex VII
Equipment category 2 of equipment-group II, explosive atmosphere due to gases, vapours or mists – [electrical equipment]	Conformity to type based on product quality assurance (module E)	Annex VII
Protective systems	Conformity to type based on quality assurance of the production process (module D)	Annex IV

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Product / Product Group	Module / article	Conformity assessment procedure
Components	Conformity to type based on quality assurance of the production process (module D)	Annex IV
	Conformity to type based on product quality assurance (module E)	Annex VII