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: **25-05-2023** to **01-03-2027** Replaces annex dated: **18-04-2023**

**Voluntary withdrawal for the crossed out activities as of 18-04-2023**

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

**Head Office**

Meander 1051
6802 ED
Arnhem
The Netherlands

| Location | Certification Scheme |
|---|---|
| Meander 1051<br>6802 ED<br>Arnhem<br>The Netherlands | ISO 9001<br>ISO 13485<br>~~Directive 2014/34/EU~~ |
| 1850 Gateway Blvd – Suite<br>925 Concord, CA, 94520<br>USA (West) | ISO 9001<br>ISO 13485<br>EN ISO 13485 |
| Tzur 8. 4486200 Tzur Yigal<br>Israel | ISO 9001<br>ISO 13485<br>EN ISO 13485 |
| K.K., West Wing 7F,<br>1-28-10 Akebono-Cho,<br>Tachikawa-shi, Tokyo,<br>Japan | ISO 9001<br>ISO 13485<br>EN ISO 13485 |
| 5F, No. 250, Jiangchangsan Road,<br>Shanghai, 200436,<br>P. R. China | ISO 9001<br>ISO 13485<br>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:<br><br>(reference to IAF-codes and NACE Rev. 2 where relevant)<br><br>12 chemicals, chemical products and fibres<br>14 rubber and plastic products<br>17 basic metals and fabricated metal products<br>18 machinery and equipment<br>19 electrical and optical equipment<br>29 wholesale and retail trade, repair of motor vehicles, motorcycles and personal and household goods<br>34 engineering services<br>35 other services |
| ISO 13485 | Medical devices — Quality management systems — Requirements for regulatory purposes for the scopes:<br>1.1 - Non-active medical devices<br>- General non-active, non-implantable medical devices<br>- Non-active implants<br>- Devices for wound care<br>- Non-active dental devices and accessories<br>- Non-active medical devices other than specified above<br>1.2 - Active (non-implantable) medical devices<br>- General active medical devices<br>- Devices for imaging<br>- Monitoring devices<br>- Devices for radiation therapy and thermotherapy<br>- Active (non-implantable) medical devices other than specified above<br>1.3 - Active implantable medical devices<br>- General active implantable medical devices<br>- Implantable medical devices other than specified above<br>1.4 - In Vitro Diagnostic Medical Devices<br>- Reagents and reagent products, calibrators and control materials for:<br>Clinical Chemistry<br>Immunochemistry (Immunology)<br>Haemotology/Haemostasis/Immunohematology<br>Microbiology<br>Infectious Immunology<br>Histology/Cytology<br>Genetic Testing<br>- In Vitro Diagnostic Instruments and software<br>- IVD Medical Devices other than specified above<br>1.5 - Sterilization Methods for Medical Devices<br>- Ethylene oxide gas sterilization (EOG)- including applicable |

[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] |
|---|---|
| | quality management system requirements within ISO 11135<br>- Moist heat - including applicable quality management system requirements within ISO 17665-1<br>- Aseptic processing<br>- Radiation sterilization (e.g. gamma, x-ray, electron beam) - including applicable quality management system requirements within ISO 11137-1<br>-Low temperature steam and formaldehyde sterilization<br>-Thermic sterilization with dry heat<br>-Sterilization with hydrogen peroxide<br>-Sterilization method other than specified above<br>1.6 - Devices incorporating/utilizing specific substances/technologies<br>- Medical devices incorporating medicinal substances<br>- Medical devices utilizing tissues of animal origin<br>- Medical devices incorporating derivates of human blood<br>- Medical devices utilizing micromechanics<br>- Medical devices utilizing nanomaterials<br>- Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed<br>1.7 - Parts and Services<br>- Raw materials<br>- Components<br>- Subassemblies<br>- Calibrations services*<br>- Distribution services<br>- Maintenance services<br>- Transportation services<br>- Other services<br>*organizations providing calibration services should be accredited to ISO/IEC 17025 |

| Product / Product Group | Module / article | Conformity assessment procedure |
|---|---|---|
| ~~**Directive 2014/34/EU**~~<br>~~**Equipment and protective systems intend for use in potentially explosive atmospheres**~~<br>~~*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~~ |

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| Product / Product Group | Module / article | Conformity assessment procedure |
|---|---|---|
| ~~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~~ |
| ~~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~~ |