

Annex to declaration of accreditation (scope of accreditation)
Normative document: EN ISO/IEC 17025:2017
Registration number: **L 571**

of **Kalibra International B.V.**

This annex is valid from: **19-01-2023** to **01-03-2027**

Replaces annex dated: **04-05-2022**

Location(s) where activities are performed under accreditation

Head Office

Delftechpark 19
2628 XJ
Delft
The Netherlands

Location	Abbreviation/ location code
Delftechpark 19 2628 XJ Delft The Netherlands	DE
On-site at the customer	O

No.	Material or product	Type of activity¹	Internal reference number	Location
1	Controlled environments with limited viable- and /or non-viable airborne particles and / or cleanrooms	Measuring particle concentration and particle size distribution; Airborne particle count test	PR-VAL-004 GMP Vol 4 Annex 1 (March 2009) and EN ISO 14644-3	O

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

J.A.W.M. de Haas

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

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No.	Material or product	Type of activity ¹	Internal reference number	Location
2	Controlled environments with limited viable- and /or non-viable airborne particles and / or cleanrooms	Installed filter system leakage test; aerosol test	PR-VAL-003 EN ISO 14644-3	O
3		Measuring particle concentration and particle size distribution; Airborne particle count test	PR-VAL-005 GMP Vol 4 Annex 1 (March 2009) and EN ISO 14644-3	O
4		Measuring airflow velocity, airflow volume and room volume to calculate air change rates	PR-VAL-006 EN ISO 14644-3	O
5	Operating theatres and rooms for laying-up of sterile instruments	Airborne Particle Count test, Segregation test and Airborne Particle Recovery test	PR-VAL-016 VCCN Guideline 7	O
6	Controlled temperature area (warehouses and rooms)	Temperature- and relative humidity mapping of environmental conditions.	PR-VAL-013 own method WHO Technical report Serie No. 961	O
7	Controlled temperature chamber (equipment)	Temperature- and relative humidity mapping of environmental conditions.	PR-VAL-017 own method IEC 60068-3-5 IEC 60068-3-7	O