

Date
 2024-10-10

Reference
 2024/2030

Scope of accreditation

Testing according to SS-EN ISO/IEC 17025:2018

RISE Research Institutes of Sweden AB Borås
 Metodik, textil och medicinteknik

Accreditation number 1002
 A002626-004

Biological examinations

<i>Method</i>	<i>Parameter</i>	<i>Technique</i>	<i>Material</i>	<i>Flex</i>	<i>Type of flex</i>	<i>Field</i>
SS-EN ISO 10993-12	Cytotoxicity		Medical devices	Yes	2	No
SS-EN ISO 10993-5	Cytotoxicity	Spectrophotometry	Medical devices	Yes	2	No

Microbiological analysis

Molecular biology

<i>Method</i>	<i>Parameter</i>	<i>Technique</i>	<i>Material</i>	<i>Flex</i>	<i>Type of flex</i>	<i>Field</i>
European Pharmacopeia EP 2.6.14 Bacterial endotoxin	Endotoxin	Spectrophotometry	Medical devices, biological samples	Yes	2	No
European Pharmacopoeia EP 2.6.7	Mycoplasma	qPCR		Yes	2	No

The scope of accreditation is flexible as specified in this decision. The accredited body must always retain a current list of the scope for which it is accredited.

Type of flexible scope

- 1: - Introduce new version of standard method and make editorial changes to non-standard method
- 2: - Introduce new version of standard method and make editorial changes to non-standard method - Introduce new version and modifications of non-standard method. The procedure must be equivalent - Introduce new parameter/component/characteristics - Introduce new measurement range - Introduce new material/new products/matrices - Introduce new method equivalent to methods already in the accreditation decision