

Health and environment division
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Emmace Consulting AB

Scheelevägen 22
223 63 Lund

Decision on changed accreditation

(2 appendices)

Decision

The Swedish Board for Accreditation and Conformity Assessment (Swedac) decides to change the accreditation of Emmace Consulting AB (registration number 556870-0164). The issued accreditation is of the scope detailed in Appendix 1. This decision replaces previous decisions dated 2021-12-23, case file 2021/774.

The accreditation is valid until further notice.

Basis for decision

Based on the performed assessment of Emmace Consulting AB it is Swedac's judgment that Emmace Consulting AB fulfils the accreditation requirements for the scope of accreditation detailed in Appendix 1.

The amendment refers to correction of method names and parameters.

Information concerning requirements for accreditation

An accredited body is obliged continuously to fulfil the requirements for accreditation. Failing this, Swedac may decide to withdraw the accreditation. The applicable requirements for your accreditation are detailed at www.swedac.se (<https://search.swedac.se/en/accreditations>).

Swedac performs surveillance of the accredited activities in accordance with its regulations for accreditation. The cost of the surveillance activities are borne by the accredited bodies through the payment of an annual accreditation fee. The fee regulations currently applicable are found at www.swedac.se.

Applications for extension or reduction of the scope of accreditation shall be submitted to Swedac. The application forms currently applicable are found at www.swedac.se.

This decision has been taken by the acting division manager Bente Zettergren after a hearing, detailing the pertinent particular circumstances, with case officer Tomas Persson.

Bente Zettergren

Appendices

1. Scope of Accreditation
Accreditation Certificate

Please notice that this is a translation. In case of any discrepancies between the English version and the original Swedish version the latter shall prevail.

ACKREDITERINGSCERTIFIKAT/ACCREDITATION CERTIFICATE



Ackred. nr 10501

Testing

ISO/IEC 17025

Emmace Consulting AB

Registration number 556870-0164

är ackrediterat som provningslaboratorium för uppgifter enligt bilaga 1 i beslut daterat 2022-06-20/is accredited as a testing laboratory for the scope specified in appendix 1 to decision dated 2022-06-20.

Laboratoriet är ackrediterat enligt den internationella standarden ISO/IEC 17025:2017. Ackrediteringen innebär att det ackrediterade laboratoriet har bedömts ha erforderlig kompetens och att opartiskt och konsekvent utföra ackrediterade tjänster inom de områden som definieras i bilaga 1 enligt ovan. Det ackrediterade laboratoriet ansvarar för resultat av utförd provning./*This laboratory is accredited to the International Standard ISO/IEC 17025:2017. The accreditation is a recognition of the competence for and consistent performance and impartiality in the provision of the services defined in appendix 1. The accredited laboratory is responsible for the outcome of performed testing.*

Ackrediteringen gäller tillsvidare. Styrelsen för ackreditering och teknisk kontroll (Swedac) genomför regelbundet tillsyn, och vart fjärde år en förnyad bedömning, för att bekräfta att gällande krav för ackrediteringen kontinuerligt uppfylls./*The accreditation is valid until further notice. The Swedish Board for Accreditation and Conformity Assessment (Swedac) regularly carries out surveillance, and a full reassessment every fourth year, in order to verify that the applicable requirements for accreditation continuously are fulfilled.*

Detta ackrediteringscertifikat utfärdades 2022-06-20/*This accreditation certificate was issued 2022-06-20*

Bente Zettergren,

Tf. Enhetschef enheten för miljö och hälsa/*Acting Division Manager of the Health and Environment Division*

Beslutet om ackreditering utfärdades med stöd av artikel 5.1 i Europaparlamentets och rådets förordning (EG) nr 765/2008 om krav för ackreditering och marknadskontroll m.m. och lagen (2011:791) om ackreditering och teknisk kontroll. Swedac är nationellt ackrediteringsorgan ansvarigt för bedömning av certifieringsorgan, kontrollorgan, laboratorier, miljökontrollanter, verifierings-/valideringsorgan och arrangörer av program för kompetensprövning som ansöker om ackreditering. Den här ackrediteringen har utfärdats under EA:s MLA-avtal och kan därmed betraktas som likvärdig andra ackrediteringar under EA:s MLA-avtal med samma ackrediteringsomfattning. /*Accreditation was granted in accordance with Article 5 (1) of Regulation (EC) No 765/2008 regarding accreditation and market surveillance etc. and the Act (SFS 2011:791) concerning Accreditation and Conformity Assessment. Swedac is the Swedish national accreditation body responsible for the assessment of certification bodies, inspection bodies, laboratories, environmental verifiers, validation and verification bodies and bodies for providing programme for proficiency testing applying for accreditation. This accreditation has been issued under the EA MLA and is therefore recognised as equivalent to other accreditations with the same scope of accreditation issued under the EA MLA.*

Appendix 1

Date

Reference

2022-06-20

2022/339

Scope of accreditation

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

Emmace Consulting AB

Lund

Accreditation number

10501

A014697-001

Material testing

<i>Method</i>	<i>Parameter</i>	<i>Material</i>	<i>Field</i>
SS-EN ISO 18562-2:2020	Emissions of particulate matter	Medical devices	No
SS-EN ISO 18562-3:2020	Emissions of volatile organic compounds (VOC)	Medical devices	No

Changes in the scope of accreditation are in bold.