

Management Systems Certification Body Institute for Testing and Certification, Inc. třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic www.itczlin.cz

## CERTIFICATE

No. 23 0049 SJ

We confirm on the basis of a performed audit that company

## VitroSorb AB

Medeon Science Park, 20512 Malmö, Sweden Company Reg. No.: SE556782621801

has implemented and documented a functional quality management system in compliance with the requirements of the standard

EN ISO 13485:2016

Covering the following activities:

Design, Manufacturing and Sales of Immunoadsorbers

Distribution and Sales of Hemoperfusion Columns and Accessories

The Certificate is issued on the basis of the results mentioned in Audit Report No. 233405163/2023. The Certificate validity is conditioned by positive results of surveillance audits, which the certified company committed to undergo.

During use of the Certificate the Certificate Holder undertakes to follow the Rules of Use of the Certificate. This document is publicly available on <a href="https://www.itczlin.cz">www.itczlin.cz</a>



Date of Issue:

07. 08. 2023

Valid until:

06.08.2026

Date of the first certification awarding: 07. 08. 2017

Ing. Pavel Vanek Head of Certification Body