

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.: 257642-2018-AQ-CZE-NA-PS

Initial certification date: 11 April 2019

Valid: 12 April 2022 – 11 April 2025

This is to certify that the management system of

BIOSINTEX S.R.L.

4 Vladiceasca Str., RO 077168, Snagov, Ilfov County, Romania

has been found to conform to the Quality Management System standard:

ISO 13485:2016 / EN ISO 13485:2016

This certificate is valid for the following scope:

Design, development, manufacturing, sales and distribution of sterile surgical sutures, with/ without needles.

Place and date: Høvik, 30 March 2022



For the issuing office: DNV Product Assurance AS Veritasveien 3, 1363 Høvik, Norway



Cecilie Gudesen Torp Management Representative

