

Management System Certificate

Certificate No.: 248674-2017-AQ-NA-PS; Rev 0

Project No.: PRJC-531713-2015-MSC-ROU Initial certification date: 28 June 2016

Valla until: 28 February 2019

This is to certify that the management system of:

BIOSINTEX S.R.L.

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

Complies with the requirements of:

ISO 13485:2003/NS-EN ISO 13485:2012

The Certificate is valid for the following scope:

Manufacturing and trade of sterile surgical sutures, with / without needles, surgical sterile prosthesis for soft tissues and surgical meshes for women urinary incontinence.

Place and date: Høvik, 27 October 2017



For: DNV GL NEMKO PRESAFE AS

Bjørg Synnøve Nesgård Certification Manager

The Certificate has been digitally signed.
See www.presafe.com/digital signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.