

Certificate PK16/871886

The management system of

S.C. SPD STAR S.R.L.

407155, Caseiu no. 136/C, Cluj County, Romania

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 25 March 2019 until 28 July 2022
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 01 April 2022
Issue 4. Certified since 28 July 2016

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by

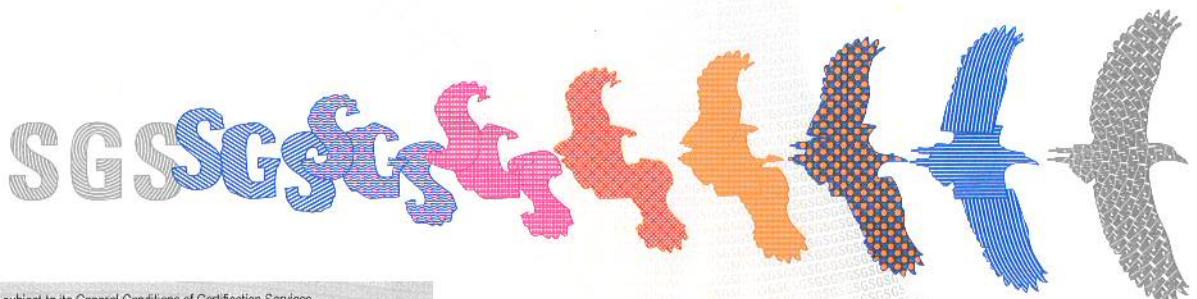


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S.C. SPD STAR S.R.L.

ISO 13485:2016
EN ISO 13485:2016



Issue 4

Detailed scope

Manufacture and sale of cotton gauze products: sterile and non sterile gauze swabs, cutting gauze, gauze bandages. Manufacture and sale of cotton wool for medical use.

**Productia si comercializarea produselor din tifon bumbac, sterile si nesterile: comprese din tifon, tifon debitat, bandaje din tifon.
Productia si comercializarea vatei hidrofile pentru uz medical**

Additional facilities

Babeni City, Uzinei Street, No.1, Valcea County, Romania



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