



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Full Quality Assurance System No. 17 0094 QS/NB

The quality system of manufacturer

Starch Medical Inc.

2150 Ringwood Avenue, San Jose, California 95131, USA

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II excluding (4)

for the following product category(ies):

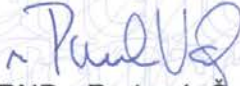
Surgical Plant Polysaccharide Haemostatic Agent

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) is required.

Valid from: 2017-03-17
Valid until: 2022-03-16
First Issued: 2017-03-17
Revision: -



Date: 2017-03-17


RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023



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třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 17 0094 QS/NB

issued for manufacturer:

Starch Medical Inc.
2150 Ringwood Avenue, San Jose, California 95131, USA

Product(s):

Name: SuperClot[®] Absorbable Polysaccharide Hemostat
Trade name(s): SuperClot[®] Absorbable Polysaccharide Hemostat
Model(s): SC0006, SC0001, SC0002, SC0003
Class: III
GMDN: 38771


Facility(ies):

Starch Medical Inc.
Legal address: 2150 Ringwood Avenue, San Jose, California 95131, USA

Starch Medical Inc.
Production site: 9th South JinGuang Street, Liangxiang Industrial Zone, Beijing, China



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issued for manufacturer:


Starch Medical Inc.
2150 Ringwood Avenue, San Jose, California 95131, USA

Certificate History:

Revision	Date	Reference Number	Action
	2017-03-17	803601910b	Certification



Date: 2017-03-17
Revision: -


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