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

EC Design-Examination Certificate
No. 19 0089 CN/NB

issued for manufacturer

Starch Medical Inc.

2150 Ringwood Avenue, San Jose, California 95131, USA

in accordance with requirements of

Directive 93/42/EEC

on medical devices, Annex II (4)

for the following product category(ies):

Surgical Plant Polysaccharide Haemostatic Agent

The Notified Body No. 1023 has performed an examination of the design dossier relating to devices / device categories in accordance with MDD Annex II. The design of the devices conforms to the requirements of this Directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

Valid from: 2019-02-27
Valid until: 2024-02-26
First Issued: 2019-02-27
Revision: -

Date: 2019-02-27

NOTIFIED BODY 1023 INSTITUTE FOR TESTING AND CERTIFICATION

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

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

Annex to EC Design-Examination Certificate

No. 19 0089 CN/NB

issued for manufacturer:

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

Product:

Name:	**PerClot® Polysaccharide Hemostatic System (PerClot® PHS)**
Trade name(s):	PerClot® Polysaccharide Hemostatic System
Model(s):	STA0001, STA0003, STA0005, STA2003, LAP3803
Class:	III
GMDN:	38771

Date: 2019-02-27
Revision: -

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Annex to EC Design-Examination Certificate

No. 19 0089 CN/NB

issued for manufacturer:

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

Certificate History:

Revision	Date	Reference Number	Action
	2019-02-27	803602705	Certification

NOTIFIED BODY 1023 INSTITUTE FOR TESTING AND CERTIFICATION

Date: 2019-02-27
Revision: -

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