Notified Body No 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlin, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 13 0984 QS/NB

Issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws) certifies that the product – medical device of Class III, type

SealFoam® Absorbable Polysaccharide Hemostat

(For detailed specification refer to Annex of this Certificate, page 1)

manufactured by company

Starch Medical Inc.

2150 Ringwood Avenue, San Jose, California 95131, USA

is manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2 of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3. and 5, of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803602011/2013, which is enclosed to this Certificate.

Condition of this Certificate use and related information:

1. *It applies only to the quality system maintained in the manufacture of the above referenced models of the medical devices and it does not substitute the design or type-examination procedures.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the **24th November 2018** at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After receiving of the complementary EC Design-Examination Certificate related to the above referenced models, and fulfilling of the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE marking followed by the number of the Notified Body according to this example:*

CE 1023

INSTITUTE FOR TESTING AND CERTIFICATION 1023 NOTIFIED BODY

RNDr. Radomír Čevelík

Issued in Zlín, on 25th November 2013 — Representative of the Notified Body No. 1023

Annex to EC Certificate
No. 13 0984 QS/NB

Issued for the company:

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

List of the medical device covered by the EC certificate:

Name	Ref. No.	Size (mm) Length × Width × Thickness
SealFoam® Standard	PF644	60 × 40 × 4
SealFoam® HD	PF432	40 × 30 × 2
	PF642	60 × 40 × 2
	PD644	60 × 40 × 4
	PD154	100 × 50 × 4
SealFoam® Sternal	PFS01	120 × 25 × 2
	PFS02	120 × 25 × 4
SealFoam® Dental	PFD01	14 × 7 × 2
	PFD02	14 × 7 × 7
SealFoam® ENT	PFE01	14 × 7 × 4

INSTITUTE FOR TESTING AND CERTIFICATION 1023 NOTIFIED BODY

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