

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

EC Design-Examination Certificate No. 13 0685 CN/NB

issued for manufacturer

Foosin Medical Supplies Inc., Ltd.

No. 20 Xingshan Road, Weihai Torch Hi-Tech Science Park, 264210 Weihai, Shandong Province, People's Republic of China

in accordance with requirements of

Directive 93/42/EEC

on medical devices, Annex II (4)

for the following product category(ies):

Synthetic Absorbable Suture

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: 2018-07-31 Valid until: 2023-07-30 First Issued: 2013-08-05

Revision: a

Date: 2018-07-31



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



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Annex to EC Design-Examination Certificate

No. 13 0685 CN/NB

issued for manufacturer:

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No. 20 Xingshan Road, Weihai Torch Hi-Tech Science Park,
264210 Weihai, Shandong Province, People's Republic of China

Product:

Name: Synthetic Absorbable Sutures

Trade name(s): WEGO-PDO

Model(s): EP 0.5~5 [USP 7-0~2]; with or without needles

Class: III 16584

Name: Synthetic Absorbable Sutures

Trade name(s): WEGO-PGA

Model(s): EP 0.4~6 Braided suture / EP 0.2~0.3 Monofilament

[USP 10-0~3 or 4]; with or without needles

Class:

GMDN: 13908

Name: Synthetic Absorbable Sutures

Trade name(s): WEGO-PGLA

Model(s): EP 0.4~6 [USP 8-0~3 or 4]; with or without needles

Class:

GMDN: 17471

Date: 2018-07-31

Revision: a

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Certificate History:

Revision	Date	Reference Number	Action
	2013-08-05	803602002	Certification
а	2018-07-31	803602667	Re-certification process

KEO SUITUITE

Date: 2018-07-31 Revision: a RNDr. Radomír Čevelík Representative of the Notified Body No. 1023

Page 2/2