EU Quality Management System Certificate BE24/00000301

The management system of

Bedal International NV

Agoralaan A bis, 3590 Diepenbeek, Belgium
SRN Number: BE-MF-000001242

has been assessed and certified as meeting the requirements of

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I)

For the following products
The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 27 November 2024 until 27 November 2029 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 27 May 2029

Issue 1. Certified since 27 November 2024

Authorised by
Virginie Siloret
Global Medical Device
Certification Manager
SGS Belgium NV NB1639
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EU Quality Management System Certificate BE24/00000301, continued

Bedal International NV

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I)

Class 1s device

MDN1214 ,MDS 1005

Sterile, single use patches for stabilization of catheters, tubing and cables.
[Basic UDI-DI: 5430000258FlexGRIPSAF]

Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on following reports: - BE/AMD/8/1085.QMD - S2A 1.19
Authorized representative name and address (if relevant): N/A
Previous certificate number: N/A
Change in between this certificate and previous one: N/A

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