

EU Quality Assurance Certificate BE24/00000031

The management system of

Hubert De Backer n.v.

Laagstraat 59, 9140 Temse, Belgium

SRN Number: BE-MF-000020418

has been assessed and certified as meeting the requirements of

MDR EU Quality Assurance certificate (Annex XI Part A)

For the following products

Class 1m device (MDS 1010)

Non -active, non-implantable, non-sterile plastic oral and vaginal dosing applicators for administration of medication
[MDN1202 – Basic UDI-DI: 5400995DosingApplicatorSD]

Conditions for & limitation to the validity of the certificate:

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).

For placing on the market of Class IIb or Class III devices covered by this certificate an EU Type Examination Certificate according to Annex X is required.

List of examinations and tests performed, which may include reference to relevant CS and harmonized 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/AND/211542 - CTC 8.13

Previous certificate number: N/A

Change in between this certificate and previous one: The recertification date has been changed from August 2029 - August 2028

This certificate is valid from 21 February 2024 until 09 February 2029 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 09 August 2028

Issue 2. Certified since 09 February 2024

Certified activities performed by additional sites are listed on subsequent pages.



Authorised by

Virginie Siloret

Global Medical Device Certification
Manager

SGS Belgium NV NB 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium

t +32 (0)3 545-48-48 - www.sgs.com

This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | [SGS](#). Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.



EU Quality Assurance Certificate BE24/00000031, continued
Hubert De Backer n.v.



MDR EU Quality Assurance certificate (Annex XI Part A)

Issue 2
Sites
Hubert De Backer n.v. Laagstraat 59, 9140 Temse, Belgium
Hubert De Backer n.v. Duitslandstraat 21, 9140 Temse, Belgium

This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | [SGS](#). Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.

