EC Certificate Production Quality Assurance System: Certificate BE19/819943433

The management system of

Hubert De Backer n.v.

Laagstraat 59
9140 Temse, BE

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V
Restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.

For the following products

The scope of registration appears on page 2 of this certificate

This certificate is valid from 14 May 2021 until 26 July 2023
and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 09 March 2005

Certification is based on reports numbered BE/AND/ 211542

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-49 www.sgs.com

Hubert De Backer n.v.

Directive 93/42/EEC

on medical devices, Annex V
Restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.

Issue 3

Detailed scope

Non-sterile plastic dosing applicators for administration of medication.

Where the above scope includes Class IIb or Class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in Addition to this certificate to place the device on the market.

Additional facilities

Duitslandstraat 21
9140 Temse, Belgium

Hubert De Backer nv
Laagstraat 59
9140 Temse
Belgium

18 Jul 2023

Confirmation Letter Reference: CLNB1639 – BE/AND/21/1542.QMD

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Hubert De Backer nv
Laagstraat 59
9140 Temse
Belgium
SRN Number: BE-MF-000020418

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15th March 2023, this letter also confirms that:

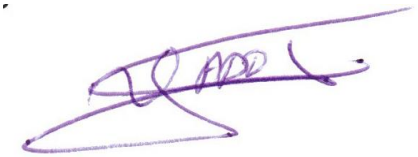
- The manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices

- 31st December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV 1639,



pp [Jérôme JADOT]

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

Devices covered by this letter:

Device name / Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Non-sterile plastic dosing applicators for administration of medication. 5400995DosingApplicatorSD	Class I devices with a measuring function	N/A	Certificate number: BE19/819943433, Issue: 3, NB1639

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/07/18	Version 1	Initial issue