Certificate BE19/819943434

The management system of

Hubert De Backer n.v.

Laagstraat 59 9140 Temse, Belgium

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 27 July 2020 until 26 July 2023 and remains valid subject to satisfactory surveillance audits.

Issue 3. Certified since 19 April 2018 and first certified by SGS Belgium since 03 April 2019

Recertification audit due before 09 June 2023

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

Authorised by

Pleter Weterings Certification Manager

SGS Belgium NV

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

ELAC

Accreditation Number

005-QMS EN ISO/IFC 17021-1-2015

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Certificate BE19/819943434, continued



Hubert De Backer n.v.

ISO 13485:2016 EN ISO 13485:2016



Issue 3

Detailed scope

Design and development, manufacturing (in ambient and cleanroom environment), warehousing and distribution of non-sterile, non-active non-implantable plastic medical devices, including plastic measuring and dosing medical devices for the administration of medication.

Additional facilities

Duitslandstraat 21, 9140 Temse, Belgium

Warehousing and distribution of non-sterile, non-active non-implantable plastic medical devices.



005-QMS





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