

Certificate BE23/00000317

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

Design, development, manufacturing and sales of non-sterile plastic oral and vaginal dosing applicator with and without measuring function for the administration of medication, nonsterile plastic cups, nonsterile plastic plugs (PIBAs – Press In Bottle Adapters), and nonsterile plastic cups, non-sterile plastic eye shields and non-sterile plastic medical device components.

Design, development and manufacturing of moulds used for manufacture of medical device and medical device components.

Subcontract manufacturing for nonsterile plastic medical devices and nonsterile plastic medical device components.

This certificate is valid from 17 October 2023 until 17 October 2026 and remains valid subject to satisfactory surveillance audits.

Issue 1. Organization certified since 19 April 2018 and first certified by SGS under UKAS since 17 October 2023.

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

Last certificate expiry date 26 July 2023

Recertification audit date 17 October 2022



Authorised by

Jonathan Hall

Global Head - Certification Services

SGS United Kingdom Ltd

Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

t +44 (0)151 350-6666 - 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.



Hubert De Backer n.v.

ISO 13485:2016

EN ISO 13485:2016

Issue 1
Sites
Hubert De Backer n.v. Laagstraat 59, 9140 Temse, Belgium Design, development, manufacturing and sales of non-sterile plastic oral and vaginal dosing applicator with and without measuring function for the administration of medication, nonsterile plastic cups, nonsterile plastic plugs (PIBAs – Press In Bottle Adapters), and nonsterile plastic cups, non-sterile plastic eye shields and non-sterile plastic medical device components. Design, development and manufacturing of moulds used for manufacture of medical device and medical device components. Subcontract manufacturing for nonsterile plastic medical devices and nonsterile plastic medical device components.
Hubert De Backer n.v. Duitslandstraat 21, 9140 Temse, Belgium Design, development, manufacturing and sales of non-sterile plastic oral and vaginal dosing applicator with and without measuring function for the administration of medication, nonsterile plastic cups, nonsterile plastic plugs (PIBAs – Press In Bottle Adapters), and nonsterile plastic cups, non-sterile plastic eye shields and non-sterile plastic medical device components. Design, development and manufacturing of moulds used for manufacture of medical device and medical device components. Subcontract manufacturing for nonsterile plastic medical devices and nonsterile plastic medical device components.



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.

