

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 applicators with and without a measuring function for administration of medication, non-sterile plastic plugs (PIBAs – Press In Bottle Adapters), and non-sterile plastic cups, non-sterile plastic eye shields and non-sterile plastic medical device components.

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

Subcontract manufacturing for non-sterile plastic medical devices and non-sterile plastic medical device components.

This certificate is valid from 22 April 2024 until 17 October 2026 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 17 October 2023

Organization certified since 19 April 2018 and first certified by SGS on 17 October 2023.

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

Authorised by

Jonathan Hall

Global Head - Certification

Services

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Certificate BE23/00000317, continued  
**Hubert De Backer n.v.**



**ISO 13485:2016**  
**EN ISO 13485:2016**

Issue 2

**Sites**

Hubert De Backer n.v.  
Laagstraat 59, 9140 Temse, Belgium

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

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

Subcontract manufacturing for non-sterile plastic medical devices and non-sterile 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 applicators with and without a measuring function for administration of medication, non-sterile plastic plugs (PIBAs – Press In Bottle Adapters), and non-sterile plastic cups, non-sterile plastic eye shields and non-sterile plastic medical device components.

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