



Certificate BE19/819943668.00

The management system of

PLASTIFLEX GROUP n.v.
also doing business as
PLASTIFLEX HEALTHCARE
and **PLASTIFLEX HEALTHCARE CHINA**

Buntjesstraat 13
3583 Paal-Beringen, 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 28 May 2022 until 27 May 2025
and remains valid subject to satisfactory surveillance audits.

Issue 3. Certified since 28 May 2010

Recertification audit due before 27 April 2025

Multiple certificates have been issued for this scope.
The main certificate is numbered BE19/819943668.00

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



Authorised by

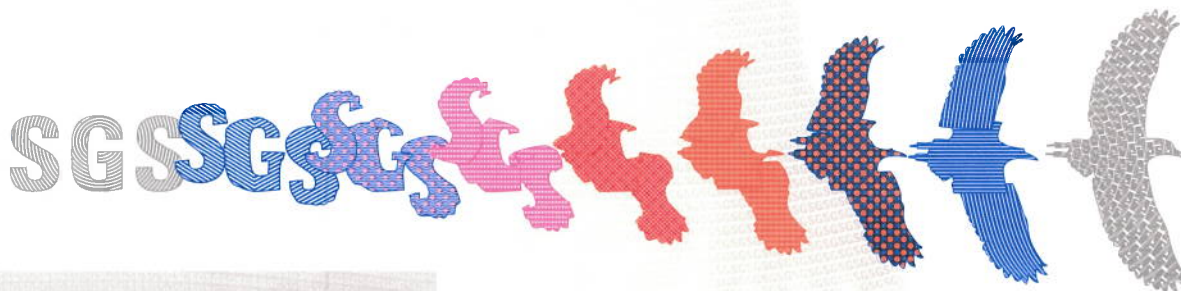
Pieter Weterings
Certification Manager

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Accreditation Number
005-QMS
EN ISO/IEC 17021-1:2015
007 QS

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ISO 13485:2016
EN ISO 13485:2016

Issue 3

Detailed scope

Design, development, manufacture and distribution of breathing circuits for respiratory care intended to carry gasses to and from the patient airway.

Dongguan Plastiflex Hose Technology Ltd.,

**No. 95 Qiaozhi Avenue, Qiaozhi Industrial District, Changping Town,
Dongguan City, Guangdong Province, 523572, P.R.China**



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