

EC Certificate Full Quality Assurance System: Certificate BE19/819943667

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

**Directive 93/42/EEC**

on medical devices, Annex II (excluding Section 4)

For the following products

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

This certificate is valid from 29 October 2019 until 24 May 2024  
and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 28 May 2010  
and first certified by SGS Belgium on 17 September 2019

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

Certification is based on reports numbered BE/AND 09/1192.QMD

Authorised by

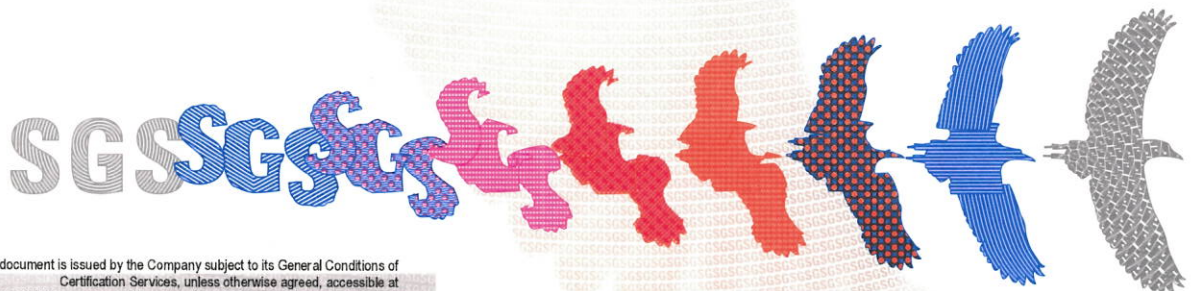
Pieter Weterings  
Certification Manager

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LPMD5007 - Certificate CE1639 Annex II-4\_EN rev. 02

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**Directive 93/42/EEC**  
on medical devices, Annex II (excluding Section 4).

Issue 2

Detailed scope

**Non-heated breathing tubes as part of circuits for respiratory care  
intended to carry gasses to and away from the patient airway,  
for neonatal, paediatric and adult use.**

Additional facilities

**Plastiflex Healthcare China,**

**Qiaozhi Industrial District, Changping Town, Dongguan City,  
Guangdong Province , 523752, P.R.China**

