

EC Certificate Full Quality Assurance System: Certificate FR19/81843429

The management system of

# **MICROVAL SAS**

Z.A. de Champ de Berre, 43240 Saint-Just-Malmont, France

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 27 January 2021 until 24 May 2024 and remains valid subject to satisfactory surveillance audits. Issue 4. Certified since 10 October 2016 and first certified by SGS Belgium NV since 16 January 2020

Certification is based on reports numbered FR/MD 233110

Authorised by

mension

Global Medical Devices Certification Manager

### SGS Belgium NV, Notified Body 1639

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

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

Page 1 of 2



This document is issued by the Company subject to its General Conditions of Certification Services, unless otherwise agreed, accessible at www.sgs.com/terms\_and\_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at https://www.sgs.com/en/certifiedclients-and-products/certified-client-directory. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.



Certificate FR19/81843429 continued

### **MICROVAL SAS**

## **Directive 93/42/EEC**

on medical devices, Annex II (excluding Section 4)

Issue 4

Detailed scope

Sterile set for nitinol staples (dispenser and staples for surgery). Sterile single use instruments for the laying of implantable uro-gynaecologic meshes.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Page 2 of 2

This document is issued by the Company subject to its General Conditions of Certification Services, unless otherwise agreed, accessible at www.sgs.com/terms\_and\_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at https://www.sgs.com/en/certifiedclients-and-products/certified-client-directory. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.



Corrigendum to Certificate FR19/81843429

# **MICROVAL SAS**

Z.A. de Champ de Berre, 43240 Saint-Just-Malmont, France

Scope:

#### Sterile set for nitinol staples (dispenser and staples for surgery). Sterile single use instruments for the laying of implantable uro-gynaecologic meshes.

This corrigendum is only valid together with accompanying 93/42/EEC certificate Issue 4

Correction Date	Correction
Change approved by SGS on 20 October 2021	Scope change to reinstate devices that were withdrawn by error on version 4: "Sterile knitted, woven or non-woven, silicone coated or not, reinforcement implants for inguinal, umbilical and hiatal hernias & eventration repair.
	Sterile set for nitinol staples (dispenser and staples for surgery).
	Sterile single use instruments for the laying of implantable uro-gynaecologic meshes."

Authorised by

Global Medical Devices Certification Manager

### SGS Belgium NV, Notified Body 1639

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

LPMD5105 - Corrigendum to Certificate

Page 1 of 1

Certification and Business Enhancement Maatschappelijke Zetel/Siège Social: Noorderlaan 87 B-2030 Antwerpen/Anvers t +32 (0)3 545 48 48 f +32 (0)3 545 48 49 www.be.sgs.com

SGS Belgium NV

Member of the SGS Group

RPR Antwerp VAT - BE 0404.882.750 Citibank BE87 5701 3412 5594

This document is issued by the Company subject to its General Conditions of Certification Services, unless otherwise agreed, accessible at www.sgs.com/terms\_and\_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at https://www.sgs.com/en/certified-clients-and-products/certified-client-directory. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.