

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

Global Medical Devices Certification Manager

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
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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.

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Scope change to reinstate devices that were withdrawn by error on version 4: “Sterile knitted, woven or non-woven, silicone coated or not, reinforcement implants for inguinal, umbilical and hiatal hernias &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

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SGS Belgium NV

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