

# Certificate

## Full Quality Assurance System Approval

Annex II excluding (4) of the Directive on Medical Devices



ECM, Bismarckstr. 106, 52066 Aachen, notified to EC under 0481 hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of annex II excluding (4) of the Directive 93/42/EEC.

This certificate is issued on behalf of:

Manufacturer

**YouMedical BV**

**Barbara Strozzilaan 201, 1083HN Amsterdam, The Netherlands**

ECM certifies that the full quality assurance system under which the products listed in annex I to this certificate are manufactured conforms with the requirements of annex II excluding (4) of the Directive 93/42/EEC on medical devices.

The approved quality assurance system is subject to periodic surveillance as defined by annex II excluding (4), section 5.

This Certificate is only valid for the products mentioned above. Special terms of validity are described in annex I to this certificate.

Any substantial changes of the quality assurance system or the listed products which might affect conformity to annex II of the Directive 93/42/EEC have to be notified to ECM and are subject to a separate assessment.

**Audit Report Number**

**572-18-131**

**Registered under**

**Z/18/04179E**

**Valid until**

**February 4<sup>th</sup>, 2023**

Aachen, February 5<sup>th</sup>, 2018

  
Certification Body





## Annex I of Certificate Z/18/04179E

Page 1 of 1



This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type	Nomenclature code <sup>1</sup>
Single use devices	bio-adhesive flora-regulating products for rectal tissue treatment	46206
Single use devices	multi-skin products; multi-effective in the treatment of irritations, rashes and eczema	46206

Special terms of validity:

None.

<sup>1</sup> UMDS Code is optional