



# EC CERTIFICATE

## Kapasa Medizintechnik GmbH

RIZ, Kapuzinergasse 6  
Waidhofen/Ybbs 3340 AUSTRIA

## Production Quality Assurance System Approval Certificate

Annex V, section 3 of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:

**The manufacture of sterile single-use medical devices for male circumcision**

Device Classifications:

**Class IIa**

Device Descriptions and Model Type:

**Please refer to Attachment: 1**

We hereby declare that an examination of the production quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex V of Council Directive 93/42/EEC on Medical Devices. We certify that the production quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 93/42/EEC, Annex V, Section 4. For Class IIb & III devices where they are covered by this certificate, an EC Design Examination certificate according to 93/42/EEC, Annex III is required. This certificate is issued with 1 attachment listing product references covered by this certificate.

File Number	A28618	Cycle Start Date	December 14, 2018
Certificate Number	1902.181214	Effective Date	December 14, 2018
Initial Issue Date	December 14, 2018	Expiry Date	December 13, 2023

Authorised by

Paul Daysh

Medical Notified Body Operations Manager  
For and on Behalf of UL International (UK) Ltd



Check Certificate  
Status: [here](#)

Notified Body  
**0843**

MDD A5 S3 PQ  
00-MB-S0043 Issue: 15.0

UL International (UK) Limited  
Wonersh House, The Guildway, Old Portsmouth Road,  
Guildford, Surrey, GU3 1LR, United Kingdom



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### Attachment 1 of 1

The products detailed below are covered under the scope of this certificate:

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Male circumcision device	UNICIRC	UNICIRC sizes A to F, R, Q	Class IIa	38525

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