By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 651207**

Issued To: **Medicem Technology s.r.o.**
Karlovarska trida 20
Kamenne Zehrovice
27301
Czech Republic

In respect of:

Design and manufacture of sterile hygroscopic cervical dilators.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2016-09-28** Date: **2019-05-27** Expiry Date: **2024-05-26**

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Supplementary Information to CE 651207

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Medicem Technology s.r.o.
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Number	Device Name	Intended purpose per IFU
Class IIa		
34965 – Cervical Dilator	Dilapan-S, Dilasoft	The devices are intended for use wherever cervical softening and dilation are desired, such as cervical ripening prior to labor induction, cervical preparation prior to termination of pregnancy or other instrumentation of the uterine cavity, etc.

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