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Zentralstelle der Länder  
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bei Arzneimitteln und  
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Product Service

# EC Certificate

Production Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex V  
(Devices in Class IIa, IIb or III)

**No. G2 072037 0013 Rev. 00**

**Manufacturer:** **Advanced Surgical Concepts Ltd**

Unit 1 & Unit 4 Sunnybank Centre  
Upper Dargle Road  
Bray, Co. Wicklow A98 E339  
IRELAND

**Product Category(ies):** **Laparoscopic Instrument Port  
Laparoscopic instrument port with  
morcellation containment system.**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

**Report No.:** 75947307

**Valid from:** 2020-03-25  
**Valid until:** 2024-05-26

**Date,** 2020-03-25

Christoph Dicks  
Head of Certification/Notified Body