



# EC-CERTIFICATE

(Production quality assurance)



This is to certify that the company

## Sonogel Vertriebs GmbH

Otto-Hahn-Straße 24  
65520 Bad Camberg  
Germany

has implemented and maintains a quality assurance system which applies to the manufacture and final controls of the products.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

### Annex V of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Ultrasound gel sterile (Class Is)

The manufacturer is subject to surveillance according to Annex V, Section 4. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

|                              |            |
|------------------------------|------------|
| Certificate registration no. | 064156 MR5 |
| Certificate unique ID        | 170644202  |
| Effective date               | 2016-10-04 |
| Expiry date                  | 2021-10-03 |
| Frankfurt am Main            | 2016-06-27 |

### DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.