



EC-CERTIFICATE

(Full quality assurance system)

DQS Medizinprodukte GmbH

hereby certifies that the company

osmed gmbh

Ehrenbergstraße 11
98693 Ilmenau
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

An audit, documented in a report, performed by DQS, has verified that this quality assurance system fulfils the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Tissue expander with or without silicon shell for temporary or permanent implantation incl. application devices according to annex

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate.

Certificate registration no.	071050 MR2
Certification ID	170501862
Date of certification	2010-07-19
Valid until	2015-07-18

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Head of Certification Body

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



**Annex to Certificate
Registration No. 071050 MR2
Certificate ID 170501862
(Issued: 2010-07-19)**

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Product name:

Tissue Expander – Sphere
from 0,24 ml to 40 ml

Tissue Expander – Hemisphere
from 0,4 ml to 2,0 ml

Tissue Expander – Rectangle
from 5 ml to 650 ml

Tissue Expander – Round
from 200 ml to 650 ml

Tissue Expander – Pin
from 0,24 ml to 0,9ml

Tissue Expander – Cylinder
from 0,24 ml to 5 ml

Tissue Expander – Cupola
from 0,35 ml to 1,5 ml

Application device Trocar

Additional product name:

Orbita Expander from 1 ml to 5 ml

Socket Expander from 0,4 ml to 2,0 ml

Tissue Expander Cylinder Dental
from 0,24 ml to 5 ml

Tissue Expander Cupola Dental
from 0,35 ml to 1,5 ml