



EC-CERTIFICATE

(Full quality assurance system)



This is to certify 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.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills 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 Identification 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. 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.	071050 MR2
Certificate unique ID	170620035
Effective date	2015-07-06
Expiry date	2020-07-05
Frankfurt am Main	2015-07-06

DQS Medizinprodukte GmbH

Frank Graichen
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main, Tel. +49 (0) 69 95427-263, medical.devices@dqs.de

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



Annex to Certificate
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Product Category	Product Name	Class	GMDN
Tissue Expander	Sphere/Orbita (temporary and permanent)	IIb	45187
	Hemisphere/Socket (temporary and permanent)	IIb	45187
	Rectangle (temporary)	IIb	45187
	Round (temporary)	IIb	45187
	Pin (temporary and permanent)	IIb	45187
	Cylinder/Cylinder Dental (temporary)	IIb	45187
	Cupola/ Cupola Dental (temporary)	IIb	45187
	Ellipsoid (temporary and permanent)	IIb	45187
Application Devices	Trocar	IIa	14154