



Declaration of Conformity

According to the Directive 93/42/EEC concerning medical devices we,

osmed gmbh
 Ehrenbergstraße 11
 98693 Ilmenau, Germany

declare on our own responsibility, that the product described is in conformity with the applicable provisions of Directive 93/42/EEC from 14.06.1993 (Annex I and Annex II).

Tissue Expander with or without silicone shell for temporary or permanent implantation (Osmosis Expander)

Product name	Additional Product name
Tissue Expander –Sphere from 0,24 ml to 40 ml	Orbita Expander from 1 ml to 5 ml
Tissue Expander –Hemisphere from 0,4 ml to 2,0 ml	Socket Expander from 0,4ml to 2,0 ml
Tissue Expander –Rectangle from 5 ml to 650 ml	
Breast Tissue Expander –Round from 200 ml to 650 ml	
Tissue Expander –Pin from 0,24 ml to 0,9 ml	
Tissue Expander –Cylinder from 0,24 ml to 5 ml	
Tissue Expander –Cupola from 0,35 ml to 1,5 ml	
Application device Trocar	

As set out in section 5, Annex II, of said directive, the manufacture of these devices is subject to surveillance.

Declaration is valid until 30. December 2011.

Ilmenau, 30. December 2009



Michael Kircheisen
 Managing Director