

# Certificate

## Full Quality Assurance



No. CE 562288

Issued to:

Mentor  
3041 Skyway Circle North  
Irving  
Texas  
75038  
USA

In respect of:

**Design, Development and Manufacture of Breast Implants (Gel and Saline filled), Implantable Tissue Expanders, Sizers for Saline Breast Implants and Resterilizable Sizers for Gel Breast Implants**

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.

For and on behalf of the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

A handwritten signature in black ink, appearing to read 'D. W. Ford', is written over a horizontal line.

David W. Ford, Executive Director, Healthcare and Testing Services

First Issued: 10 Aug 2010

Date: 10 Aug 2010

Expiration Date: 9 Aug 2015

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*Conditions of Approval*

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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# Certificate

## History of Quality Assurance Certificate

**Certificate No:** CE 562288  
**Issue Date:** 10 Aug 2010  
**Issued to:** Mentor  
Irving  
USA

Date	Customer Reference	Action
10 August 2010	7522865	First issue, transfer from TÜV SUD (certificate number G1 07 08 24116 018)