Certificate

SQS herewith certifies that the company named below has a management system which meets the requirements of the standard specified below.

Medcem GmbH
8570 Weinfelden
Switzerland

Certified area

Whole company

Field of activity

Design and development, manufacturing and distribution of dental materials

Standard

ISO 13485:2012 Medical devices – Quality Management System

Swiss Association for Quality and Management Systems SQS
Bernstrasse 103, CH-3052 Zollikofen
Issue date: December 21, 2012

This SQS Certificate is valid up to and including December 20, 2015
Scope number 19
Registration number 36632

X. Edelmann, President SQS

R. Glauser, Managing Director SQS

SCESm 001

Swiss Made

Partner of IQNet

EC-Certificate

SQS as a conformity assessment body identification number 1250 herewith certifies the company

Medcem GmbH
8570 Weinfelden
Switzerland

the use of a quality assurance system in its design, development, manufacturing and distribution which fulfills the requirements set out in:

ANNEX II.3 Directive 93/42/EEC

This approval is based on the result of the audit documented in the report dated December 17, 2012.

The scope of validity covers the products

Class IIa
Pure Portland Cement
Medcem MTA Radio-opaque Portland Cement

The following CE label can be applied to these products

CE 1250

A condition for the validity of this certificate is a regular examination in accordance with Annex II.5 of the Directive 93/42/EEC.

Swiss Association for Quality and Management Systems SQS
Bernstrasse 103, CH-3052 Zollikofen
Issue date: December 21, 2012

This SQS Certificate is valid up to and including December 20, 2015
Registration number 36633
Approved Medical Responsible: December 19, 2012

R. Glauser, Managing Director SQS

U. Decurtins, Medical Responsible

SCESm 001
CE 1250

Swiss Made

Partner of IQNet