For better dentistry®

DENTSPLY
CAULK

L.D. Caulk Division
38 West Clarke Avenue
Milford, DE 19963-1805
(302) 422-4511

AQUASIL AND AQUASIL ULTRA - ACCESSORIES

EC Declaration of Conformity

Manufacturer's Name Address:	DENTSPLY Caulk 38 West Clarke Avenue Milford DE 19963 USA
Authorized EC Representative Name and Address:	DENTSPLY DeTrey GmbH D-78467 Konstanz Germany
Unique Product Identification:	605.78.122 Intra Oral Tips ~~605.78.121 Mixing Tips~~ 605.78.399 Auto-Mix 50
Description:	Mixing Tips - Eleven element mix tip for use with Aquasil Light Bodies. Intra Oral Tips - for use with Aquasil Light Bodies Auto-Mix 50 – Cartridge Dispenser gun
Product Classification Per Annex IX:	This product is classified as a Class I Medical Device under Annex IX Section III rule 5, transient, invasive device.

EC Declaration of Conformity:

The above listed medical device(s) conform to the requirements of Council Directive 93/42/EEC *as amended by Council Directive 2007/47/EC* and meet the relevant Essential Requirements of Annex I. All devices are designed, manufactured, tested, and released for sale in accordance with the technical documentation

This declaration is made on the basis of the Certificate of Conformity US97/10442 issued by SGS United Kingdom Ltd. Systems & Services Certification with Notified Body identification number 0120 in accordance with Annex VII of the Directive.

DENTSPLY Caulk Division maintains a quality management system that complies with the United States Food and Drug Administration 21 CFR Part 820 & 211, ISO 13485:2003, CMDR, JPAL (MO 169) and the European Union Council Directive 93/42/EEC

Authorized Signature:

Name: RSC **Date of Issuance:** 4/8/13

Rebeca Santiago
QA/RA Manager