



DENTSPLY International
Raintree Essix Glenroe
1912 44th Avenue East.
Bradenton, FL 34203
Ph: (800) 237-4060

EC DECLARATION OF CONFORMITY

<u>PRODUCT NAME</u>	<u>PART NUMBER DESIGNATOR</u>
Retainer Brite	RB-368, RB-92-Case, RB-36-Case, RB-Tablet, RB-TP

GMDN Code:	16715
Purpose /Description:	Cleanser of removable oral appliances
Device Classification:	Class I, Rule 5
Route to Compliance	Annex VII of MDD 93/42/EEC
Notified Body and ID#:	BSI 0086
CE Certificate Number:	505127

DENTSPLY International Raintree Essix Glenroe of 1912 44th Avenue East, Bradenton, FL 34203, hereby declares that the product(s) described above conform to the requirements of Council Directive 93/42/EEC and meet the relevant Essential Requirements of Annex I.

AUTHORIZED REPRESENTATIVE

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Date: 18/01/2011

Signature: _____


Charles Simpson
QARA Manager

DENTSPLY International Raintree Essix Glenroe maintains a Quality Management System in substantial compliance with the United States Food and Drug Administration 21 CFR Part 820, ISO 13485:2003, and the European Union Council Directive