Danville

ZEST DENTAL SOLUTIONS

ZEST | DANVILLE MATERIALS | PERIOSCOPY

# DECLARATION OF CONFORMITY

| | | |
|---|---|---|
| LEGAL MANUFACTURER | Danville Materials<br>2875 Loker Avenue East<br>Carlsbad, CA 92010 USA | |
| AUTHORIZED REPRESENTATIVE | MDSS GmbH<br>Schiffgraben 41<br>30175 Hannover, GERMANY | |
| RESPONSIBILITY | This declaration of conformity is issued under the sole responsibility of Danville Materials | |
| PRODUCT(S) | EZ Composite Resin<br>(refer to attached product schedule) | |
| RISK CLASS | Class I | |
| CONFORMITY ASSESSMENT ROUTE | Annex VII | |
| DECLARATION | We, the manufacturer, Danville Materials, declare that the above mentioned product meets the provision of Council Directive 93/42/EEC for Medical Devices | |
| NOTIFIED BODY | N/A – not applicable to Class I devices | |
| EC CERTIFICATE | N/A – not applicable to Class I devices | |
| STANDARDS APPLIED | EN ISO 13485:2012 | Medical devices - Quality management systems - Requirements for regulatory purposes |
| | EN ISO 14971:2012 | Medical devices - Application of risk management to medical devices |
| | ISO 10993-1:2009 | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process |
| | ISO 15223-1:2012 | Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements |
| | EN 1041:2008 | Information supplied by the manufacturer of medical devices |
| | EN 980:2008 | Symbols for use in the labelling of medical devices |
| PLACE OF ISSUE | Carlsbad, CA, USA | |
| SIGNED | Mark Stavro, Director Regulatory Affairs | August 14, 2017<br>Date |

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| Part Number | Description | GMDN Code | UMDNS Code |
|---|---|---|---|
| 94792 | MIXING TIPS, MEDIUM, 17G (25) | 58399 | 26-864 |
| 94793 | MIXING TIPS, SMALL, 19G (25) | 58399 | 26-864 |
| 90-00025 | CEMENT AUTOMIX TIPS (24) | 58399 | 26-864 |