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## Annex V EC Declaration of Conformity

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|---|---|
| **Manufacturer Name and Address:** | Kerr Corporation<br>1717 W. Collins Ave.,<br>Orange, CA 92867, USA |
| **Authorized Representative Name and Address:** | Kerr Italia S.r.l.<br>Via Passanti, 174<br>Scafati (SA) 84018, Italy |
| **Technical File Name/Number:** | SonicFill 3 Tips Technical File, R014 |
| **Product Tradename(s):** | SonicFill 3 |
| **Device Identification:** | See Attachment 1 |
| **Classification and Rule(s):** | IIa per Annex IX, Rule 8 |
| **Notified Body:** | BSI Group The Netherlands B.V. |
| **Notified Body Number:** | 2797 |
| **Conformity Assessment Procedure & Certificate Issued:** | Annex V – Production Quality Assurance<br>CE Certificate Number 00847 |

**Declaration Statement:**
*We hereby declare that the above-mentioned device(s) comply with Council Directive 93/42/EEC.*

**Regulatory Affairs Signature:**

June 10, 2022
Issue date

Name: Jennifer Evans
Title: Vice President RA/QA - Consumables

Printed by GERARDO.LARA, on 14 Jul 2022 at 09:41:26 am

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**SonicFill 3 Tips – Attachment 1**
**to Annex V EC Declaration of Conformity**

| REF | Description |
|---|---|
| 36711 | SonicFill 3 Unidose Refill A1 |
| 36712 | SonicFill 3 Unidose Refill A2 |
| 36713 | SonicFill 3 Unidose Refill A3 |
| 36714 | SonicFill 3 Unidose Refill B1 |



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# MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

**PRODUCTION QUALITY ASSURANCE PROCEDURES**

This is a declaration made under **Clause 6.6** of **Schedule 3** to the Therapeutic Goods (Medical Devices) Regulations 2002.

| | |
|---|---|
| **Manufacturer Name:** | Kerr Corporation |
| **Business Address:** | 1717 W. Collins Ave., Orange, CA 92867, USA |
| **Medical Device(s):** | SonicFill 2 & SonicFill 3 |
| **Classification:** | Class IIa |
| **GMDN Code and Term:** | 35870 – Dental Composite Resin |
| **Scope of Application:** | All lots |

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and these procedures.

***Production Quality Assurance Procedures Certificate:***
Issued by British Standards Institution (BSI), Certificate No.: CE 00847 - Annex V of the Directive 93/42/EEC on Medical Devices.

***Standards Applied:***

| | |
|---|---|
| • EN ISO 1641:2009 | Dentistry - Medical devices for dentistry - Materials |
| • ISO 4049:2019 | Dentistry-Polymer-based Filling, Restorative and Luting Materials |
| • EN ISO 13485:2016/AC:2018 | Medical Devices - Quality management systems |
| • EN 1041:2008+A1 2013 | Information supplied by the manufacturer of medical devices |
| • ISO 8601-1:2019 | Date and time – Representations for Information interchange – Part 1: Basic rules |
| • EN ISO 15223-1:2016 | Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied. Part 1: General requirements |
| • EN ISO 10993-1:2020 | Biological evaluation of medical devices - Part 1: Evaluation and testing |
| • ISO 10993-2:2006 | Biological evaluation of medical devices - Part 2: Animal welfare requirements |

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|---|---|
| • EN ISO 10993-3:2014 | Biological Evaluation of Medical Devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity |
| • EN ISO 10993-5:2009 | Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity |
| • ISO 10993-6:2016 | Biological Evaluation of Medical Devices - Part 6: Tests for local effects after implantation |
| • EN ISO 10993-10:2013 | Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization |
| • EN ISO 10993-11:2018 | Biological evaluation of medical devices - Part 11: Tests for systemic toxicity |
| • EN ISO 10993-12:2012 | Biological evaluation of medical devices - Part 12: Sample preparation and reference materials |
| • EN ISO 10993-17:2009 | Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances |
| • ISO 7405:2018 | Dentistry - Evaluation of biocompatibility of medical devices used in dentistry |
| • MEDDEV 2.7/1 Rev4 | Clinical Evaluation: A Guide For Manufacturers And Notified Bodies Under Directives 93/42/EEC and 90/385/EEC |
| • EN ISO 14971:2012 | Medical devices - Application of risk management to medical devices |
| • IEC 62366-1:2015 | Medical devices - Part 1: Application of usability engineering to medical devices |
| • ASTM D4169:2016 | Standard Practice for Performance Testing of Shipping Containers and Systems |

***Authorised Signatory:***

June 10, 2022
Issue date

Name: Jennifer Evans
Title: Vice President RA/QA - Consumables



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## Schedule for GMDN 35870 – Dental Composite Resin

| REF | Description |
|---|---|
| 36051 | SonicFill 2 Unidose Refill A1 |
| 36052 | SonicFill 2 Unidose Refill A2 |
| 36053 | SonicFill 2 Unidose Refill A3 |
| 36054 | SonicFill 2 Unidose Refill B1 |
| | |
| 36711 | SonicFill 3 Unidose Refill A1 |
| 36712 | SonicFill 3 Unidose Refill A2 |
| 36713 | SonicFill 3 Unidose Refill A3 |
| 36714 | SonicFill 3 Unidose Refill B1 |



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