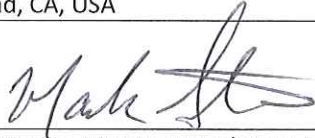



**DECLARATION OF CONFORMITY**

|                             |                                                                                                                                                                                                                                                                                                    |                                                                                                                                            |
|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| 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)                  | Microprime G<br>(refer to attached product schedule)                                                                                                                                                                                                                                               |                                                                                                                                            |
| RISK CLASS                  | Class IIa                                                                                                                                                                                                                                                                                          |                                                                                                                                            |
| CONFORMITY ASSESSMENT ROUTE | Annex II                                                                                                                                                                                                                                                                                           |                                                                                                                                            |
| 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               | BSI (NB# 0086)<br>Kitemark Court<br>Davy Avenue, Knowlhill<br>Milton Keynes, Mk5 8PP<br>United Kingdom                                                                                                                                                                                             |                                                                                                                                            |
| EC CERTIFICATE              | CE 598352<br>Expiry Date: 18 June 2023                                                                                                                                                                                                                                                             |                                                                                                                                            |
| STANDARDS APPLIED           | EN ISO 13485:2016                                                                                                                                                                                                                                                                                  | 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                                 |
|                             | EN ISO 15223-1:2016                                                                                                                                                                                                                                                                                | 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                                                                                |
| PLACE OF ISSUE              | Carlsbad, CA, USA                                                                                                                                                                                                                                                                                  |                                                                                                                                            |
| SIGNED                      | <br><hr/> Mark Stavro, Director Regulatory Affairs <span style="float: right;"> <br/> <hr/>           Date         </span> |                                                                                                                                            |



**Danville**

| <b>Part Number</b> | <b>Description</b>            | <b>GMDN Code</b> | <b>UMDNS Code</b> |
|--------------------|-------------------------------|------------------|-------------------|
| 10148              | MICROPRIME G, SAMPLE          | 45232            | 11-184            |
| 90814              | MICROPRIME G,10ML             | 45232            | 11-184            |
| 94178              | MICROPRIME G,SMPL,UD,0.2ML(2) | 45232            | 11-184            |
| 94263              | MICROPRIME G UNIT DOSE 50 PCS | 45232            | 11-184            |
| 90-00091           | MICROPRIME G 5ML SAMPLE       | 45232            | 11-184            |