

## DECLARATION OF CONFORMITY

COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

We, Oro Clean Chemie AG, Allmendstrasse 21, 8320 Fehraltorf, Switzerland, declare under our sole responsibility that the products conform to the requirements of Council Directive 93/42/EEC and meet the relevant essential requirements of Annex I.

### Concentrate for the disinfection and cleaning of dental impressions.

|                                  |                                                                                                                                                                                                                                                                            |
|----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Trade name:                      | ASEPTOPRINT® Liquid                                                                                                                                                                                                                                                        |
| Intended purpose:                | ASEPTOPRINT® Liquid is a concentrate for the disinfection and cleaning of dental impressions made of alginate, polyether, polysulfide, A-silicone, and C-silicone. ASEPTOPRINT® Liquid does not affect the dimensional stability of dental impressions. Free of aldehydes. |
| Classification:                  | Class IIa according to Annex IX of Council Directive 93/42/EEC (Rule 15)                                                                                                                                                                                                   |
| Conformity assessment procedure: | Annex II excluding section 4                                                                                                                                                                                                                                               |
| Applied standards:               | EN ISO 13485:2016 + A11:2021, EN ISO 14971:2019 + A11:2021, EN 62366-1:2015 + A1:2020, EN 14885:2022, EN ISO 10993-1:2020, EN ISO 21530:2004, EN ISO 20417:2021, EN ISO 15223-1:2021                                                                                       |

| Basic UDI-DI          | REF       | Sizes          |
|-----------------------|-----------|----------------|
| 955100144OF100016AL9Y | CH-071041 | 1 litre bottle |

|                                      |                                                                                               |
|--------------------------------------|-----------------------------------------------------------------------------------------------|
| Authorized representative in the EU: | Oro Clean Chemie s.r.o.<br>Vinohradská 2828/151<br>Žižkov<br>130 00 Praha 3<br>Czech Republic |
| Notified body:                       | DNV Product Assurance AS<br>Veritasveien 1<br>1363 Høvik<br>Norway                            |
| Identification number:               | 2460                                                                                          |
| Certificate number:                  | 10000400154-PA-NA-MYS, rev.1                                                                  |
| Issued:                              | Høvik, 30.03.2021                                                                             |
| Expires:                             | 27.05.2024                                                                                    |

Lee Moi Wong  
Chief Research Officer  
Fehraltorf  
2023.12.18  
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This signed document is valid for all translations attached.

**Killing Germs**  
for a safer world

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