

## EC DECLARATION OF CONFORMITY

We

**Cavex Holland B.V.**  
**Fustweg 5, 2031 CJ Haarlem**

declare under our own responsibility that the products

**Cavex ImpreSafe (art nr. HA050, HA053)**  
**Dental Impression Disinfectant**  
**GMDN: 31079 / 33956**

to which this declaration concerns, is in compliance with the following standard(s) or other normative document(s)

**EN1040 / EN1276 / EN13727 / EN14561 Bactericidal Activity**  
**EN1650 / EN1275 / EN13624 / EN14562 Fungicidal Activity**  
**EN14475 Virucidal Activity**  
**HIV, HBV, HCV, Infuenza, Herpes, Rota**  
**and other as mentioned in the Technical Documentation**

according to the provisions of

**Council Directive 93/42/EEC, Annex II (without 4)**  
**Concerning medical devices**

Cleaning and Disinfection Materials are Class IIa medical devices  
under rule 15 of Annex IX

Conformity assessment performed by:

**CE0197**  
**TÜV Rheinland LGA Products GmbH**  
**Tillystrasse 2, 90431 Nürnberg**

Haarlem, 6 April 2017



Richard Woortman  
Manager Technical Services

*This statement of conformity is valid in connection with the release documents for the respective batch of produced devices.*