

EC DECLARATION OF CONFORMITY

We

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

declare under our own responsibility that the products

Cavex ColorChange
GMDN: 35863

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

ISO1563 Dental alginate impression material
and other as mentioned in the Technical Documentation

according to the provisions of

Council Directive 93/42/EEC, Annex VII
Concerning medical devices

Dental Impression Materials are Class I medical devices
under rule 5 of Annex IX

Conformity assessment performed by:

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.