



EC DECLARATION OF CONFORMITY

We

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

declare under our own responsibility that the products

Optimage

GMDN:35863
UMDNS:16-676

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 2017/745, Annex XI
Concerning medical devices

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

Conformity assessment performed by:
TÜV Rheinland LGA Products GmbH
Tillystrasse 2, 90431 Nürnberg
CE0197

Haarlem, 5 November 2020

Richard Woortman
Manager Technical Services

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



EC DECLARATION OF CONFORMITY
Annex: List of Articles

Optimage

Article Number	Article Name	BASIC UDI-DI
AA697	Optimage	E241AA6971

Haarlem, 5 November 2020

Richard Woortman
Manager Technical Services