

EC DECLARATION OF CONFORMITY

We

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

declare under our own responsibility that the products

Cavex Alginate Impression Materials

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, 9 January 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.

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Annex: List of Articles

Cavex Alginate Impression Materials

Article Number	Article Name	BASIC UDI-DI
AA025	Cavex alginate CA37 Fast Set 20x500g	E241AA0251
AA035	Cavex alginate CA37 Fast Set 24x453g	E241AA0351
AA055	Cavex alginate CA37 Normal Set 24x453g	E241AA0551
AA075	Cavex alginate CA37 Normal Set 20x500g	E241AA0751
AA096	Cavex alginate Impressional Normal Set 20x500g	E241AA0961
AA097	Cavex alginate Impressional Fast Set 20x500g	E241AA0971
AA190	Cavex alginate Tulip 24x453g	E241AA1901
AA323	Cavex alginate ColorChange 20x500g	E241AA3231
AA343	Cavex alginate ColorChange 300x18g	E241AA3431
AA371	Cavex alginate Tulip Colorswitch 24x453g	E241AA3711
AA380	Cavex alginate Orthotrace 20x500g	E241AA3801
AA600	Cavex Cream alginate Normal Set 20x500g	E241AA6001
AA603	Cavex Cream alginate Normal Set 300x18g	E241AA6031
AA605	Cavex Cream alginate Fast Set 20x500g	E241AA6051
AA613	Cavex Cream alginate Fast Set 300x18g	E241AA6131

Haarlem, 9 January 2020

Richard Woortman
Manager Technical Services