



## EC DECLARATION OF CONFORMITY

We

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

declare under our own responsibility that the products

**Alginoplast, Xantalgin, Alligat**

**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 IX**  
**Concerning medical devices**

Dental Impression Materials are Class I medical devices

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

Haarlem, 21 January 2021

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

#### Alginoplast, Xantalgin, Alligat

Article Number	Article Name	BASIC UDI-DI
65692089	Xantalgin Select 40 x 500g	E241656920891
65602047	Alginoplast SH 40 x 500g	E241656020471
66002443	Xantalgin Select SH 40 x 500g Regional	E241660024431
65692097	Xantalgin Select SH 2 x 500g	E241656920971
66005222	Xantalgin Crono 2 x 500g	E241660052221
65602012	Alginoplast NH 40 x 500g	E241656020121
66005221	Xantalgin Crono 40 x 500g	E241660052211
66002444	Alginoplast SH 40 x 500g Regional	E241660024441
66018507	Alligat Chroma Fast Set 24 x 453g	E241660185071
66001763	Alligat 24 x 453g	E241660017631
66034566	Alginoplast SH 40 x 500g Korea	E241660345661

Haarlem, 21 January 2021

A handwritten signature in blue ink, appearing to read "Richard Woortman".

Richard Woortman  
Manager Technical Services