

EC DECLARATION OF CONFORMITY

Manufacturer: Cavex Holland B.V. Fustweg 5, 2031CJ Haarlem The Netherlands SRN: NL-MF-000000423	
Declares under our own responsibility that the product(s): Cavex Impressional Fast Set GMDN:35863 UMDNS:16-676	
In compliance with the following standard(s) or other normative document(s): EN ISO 21563 - Dentistry - Hydrocolloid impression materials and other as mentioned in the Technical Documentation according to the provisions of Regulation (EU) 2017/745 Concerning medical devices	
Device Class	Classification Rule including subclause according to Annex VIII
I	Rule 5
Conformity assessment performed by notified body: TÜV Rheinland LGA Products GmbH Tillystrasse 2, 90431 Nürnberg Identification number: CE0197	

Haarlem, 21-11-2023


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

Cavex Impressional Fast Set

Main product group Basic UDI-DI(EUDAMED): ++E241AA000LX		
Article Number	Article Name	Sub Group UDI-DI / L-UDI
AA097	Cavex Alginate Impressional Fast Set 20x500g	E241AA0971

Reference to the Product List and Application

The Notified Body TÜV Rheinland LGA Products GmbH confirms that the information provided on the Product List and Application- which is identical to the Annex: List of Articles on this Declaration of Conformity(DoC),-is covered by the EU conformity assessment procedure as certified by MDR (EU) certificate No: **HZ 1710455-1**

Haarlem, 21-11-2023



Richard Woortman
Manager Technical Services