Declaration Of Conformity

EU Responsible Person: ROYAL SMILE S.L.

Ctra. de Boadilla 120, Portal 2, 2° A, 28222 Majadahonda (Madrid), Spain.

Product : Gingival Barrier

Product Use : It serves as a barrier during oral treatment or assists in shaping the prosthetic devices.

Country of Origin: China

Model No. : --

Lot/Batch no.: 20260105

Declaration

This declaration of conformuty is the responsibility of manufacturer / exporter.

Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 20417:2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021

The packaging and labeling of the products comply with the requirements of Article 19 of the Directive, including:

The list of ingredients in accordance with the INCI nomenclature;

Expiry date or Period After Opening (PAO);

Usage instructions and warnings (if applicable);

Identification of the batch or batch number.

WhiteWash Laboratories
Tooth Towers
Lagonda Road
Billingham
TS23 4JA

Brand manager