



DECLARATION OF CONFORMITY

According to REGULATION (EU) 2017/745.

Manufacturer:

Company name: Coral Healthcare Products
Manufacturer Co., Ltd
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Wenchang Road, Yangzhou, China.
Tel: +86 0514-82819550
E-mail: felix@coralclean.com
SRN:CN-MF-000011818

Whose Authorized Representative:

Name: JOYSUN GROUP S.L.U
Address: CALLE ORENSE, NUM 10.
PLANTA 1.PUERTA 13, 28020 MADRID,
SPAIN.
E-mail: Joysun-yes@isosh.com
Tel: +34-689090213
SRN: ES-AR-000043666

We, the manufacturer, herewith declare that the device covered by the present EU declaration is in conformity with the (EU) MDR 2017/745.

Product Name	Chewies		
Model	S414		
Intend use	The product is intended to be placed between upper and lower orthodontic appliances. By tightening the upper and lower teeth, the invisible aligner and teeth are more closely fitted.		
CND code	Q010499	Basic UDI-DI	
Classification and rule	I, rule1	Conformity Assessment Route	Article 19, Annex II and Annex III

Applicable Standards and CS:

ISO 13485:2016
ENISO 10993-5:2009
ISO 20417:2021

ISO 14971:2019
ISO 10993-10:2021

ISO 10993-1:2018
ISO 15223-1:2021

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the REGULATION (EU) 2017/745. We agree to develop, implement and maintain a documented post-production monitoring process.

Signed:

Name of authorized signatory: Shaohua Zhu

Date: December 19, 2024

Position held in the company: General Manager

Place:Jiang su , China

Coral Healthcare Products Manufacturer Co., Ltd