EC Certificate
Production Quality Assurance

Certificate No.:	Project No.:	Valid Until:
241563-2017-CE-IBE-NA-PS Rev. 0.0	**PRJC-251369-2010-MSL-ESP**	**18 May 2020**

This is to certify that the quality system of:

ANTONI CARLES, S.A.
Volta dels Garrofers, 41-42
Pol. Ind. Els Garrofers
08340 Vilassar de Mar
Spain

For production and final product inspection/testing of:

Dental Units and Orthodontic Chairs with Accessories

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.2.b and Annex V (Module D1) of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 20 October 2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Alessandra Rinna

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replaces the Certificate 171329-2015-CE-IBE-NA Rev.4.0 (NB 0434), following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460).	2017-10-20

Products covered by this Certificate:

Product Description	Product Name	Class
Dental Delivery System, stationary GMDN: 34991	Pneumatic Dental Unit • SD-25 • SD-150, SD-150 Scandinavian • SD-140 • SD-175	IIa
	Electronic Dental Unit • SD-80, SD-80 Scandinavian • SD-300, SD-300 Scandinavian • SD-350 • SD-550 • SD-575 • SD-580	IIa
	Orthodontics Chair including an aspiration unit • ANCAR-3200 • SD-60	IIa

The complete list of devices is filed with the Notified Body

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Sites covered by this certificate

Site Name	Address
ANTONI CARLES, S.A.	Volta del Garrofers, Pol. Ind. Els Garrofers,08340,Vilassar de Mar,Spain

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate