EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
241175-2017-CE-ITA-NA-PS Rev. 0.0	**PRJC-89356-2008-MSL-ITA**	**3 August 2022**

This is to certify that the quality system of:

CERACARTA S.P.A.
Via Secondo Casadei
47122 Forlì
Italy

For design, production and final product inspection/testing of:

Defibrillation Pads and Electrosurgical Plates

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H2) 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, 2 January 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Tone Kolpus

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 for Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replaces Certificate 119223-2012-CE-ITA-NA (NB 0434), following transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460) during re-certification.	2017-12-27

Products covered by this Certificate:

Product Description	Product Name	Class
General Active Medical device	Top Plate- Defibrillation Pads 14793 DEF. PLATE E D -1010 (CF. 2PZ.) 14984 DEF. PLATE MULTI EDC 1020 CF.X 2PZ. 14985 DEF. PLATE EDC 1045 CFX 2PZ. CM 110/130 15034 DEF. PLATE MULTI EDC 1025 CF.X 2PZ. 15103 DEF. PLATE N.K. EDC -1055(CFX2) 15282 DEF. PEDIATRIC PLATE EDC-P120 15607 DEF. PLATE MOD. EDC-1045 CABLE 180CM CFX2 15608 DEF. PLATE MOD. EDC-PED.145 CABLE 110/130CM 15775 DEF. PEDIATRIC PLATE EDC - P 155 15978 DEF. ADULT PLATE EDC-1030 16029 DEF. PLATE MULTI EDC 1035(1CF.X2) 16345 DEF. PEDIATRIC PLATE PEDIATRIC EDC-P115 16489 DEF. PLATE REF. EDC-1015 CF.X 2PZ. 16766 DEF. PLATE AD EDC -1050(CFX 2) 18498 DEF. PLATE EDC-P135 18503 DEF. PLATE EDC-1060 19189 DEF. PLATE EDC-2055	IIb
Active surgical device	Top Plate- Electrosurgical plates 13447 ELECTR. UNIPOLAR ADULT PLATE 13448 ELECTR. ADULT DUAL PLATE 13449 ELECTR. UNIPOLAR PEDIATRIC PLATE 13450 ELECTR. UNIPOLAR INFANT PLATE 13451 ELECTR. PEDIATRIC DUAL PLATE 13452 ELECTR. INFANT DUAL PLATE 14986 ELECTR. UNIPOLAR AD. PLATE CABLE 3M 2500C-12 (T.PLATE) 15306 ELECTR. PLATE REF. 2700-C/12 INFANT. 2 Z. 15370 ELECTR. UNIPOLAR AD. PLATE + CABLE 2125/C-00 15402 ELECTR. AD. PLATE + CABLE 2125 C/10 (TOP PLATE) 15986 ELECTR. PEDIATRIC PLATE + CABLE 2600 C/12 (TOP PLATE) 16041 ELECTR. AD. DUAL PLATE + CABLE 2500 C/00 (B) 16090 ELECTR. INFANT PLATE REF. 2700-C/00(2 Z.) 16295 ELECTR. DUAL PLATE ADULTS REF. 2500 -C/12/05 16490 ELECTR. TOP PLATE R. 2500-C-00 CABLE 5MT. 16735 ELECTR. INFANT PLATE ELECTR.1Z 2425-C/00 16736 ELECTR. PEDIATRIC PLATE ELECTR.1Z 2225-C/00 16994 ELECTR. DUAL PLATE REF.2600-C/00-5 m TOP PLATE	IIb

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The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
CERACARTA S.p.A. Sede Legale e Operativa	Via Secondo Casadei 47122 Forlì Italy

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