



SKIN ABLATION SURGERY

FOR DERMATOLOGY AND
AESTHETIC MEDECINE


CESARE
QUARANTA


TECHNOLOGY
OF EXCELLENCE
MADE IN ITALY

Plasma 4.0[®]

NEW FORM FOR AESTHETIC MEDECINE



Plasma 4.0[®]

WHAT IS PLASMA 4.0

Plasma 4.0 is the **medical device** that exploits the principle of radio frequency to generate the “**formation of plasma**”. Thanks to its technology, **Plasma 4.0** allows you to operate **safely in different medical areas** - including **aesthetic medicine, dermatology and oculoplasty** - and guarantees to the patient, effective, minimally invasive and minimally painful treatments.

Plasma 4.0, thanks to its technical characteristics and the technology used, is a **high-end device** the use of which is **reserved exclusively to medical personnel** with excellent training and specialization in surgery that consists in the transformation and correction of biological tissues, in particular of the skin.

With **Plasma 4.0** you can **mitigate and treat most skin lesions and perform specific surgeries** through electric arc dermabrasion.

The device is equipped with a sterile needle and the simple yet practical design makes the object ergonomic and easy to handle for the operator, increasing thus the handling and flexibility of action during the treatment. The device is powered by lithium-ion batteries rechargeable in a few hours.

*the information contained in this document is aimed at health care professionals and / or medical professionals



LIGHT GUIDE SPINDLE

illuminates and facilitates the operator



EFFICIENT PERFORMANCE



LONG LASTING BATTERY

up to 5 days demonstrated with internal laboratory tests under adverse conditions



FAST CHARGING

simple to perform



DISPOSABLE NEEDLE



"FREEHAND" PLASMA PEN

without need for other media



16 PROGRAMS

adjustable in intensity based on the type of treatment



USER INTERFACE USER FRIENDLY

digital calibration on liquid crystal display



Notified Body No. 0476

Plasma 4.0

HIGH LEVEL OF
PRECISION IN THE
PERFORMANCE OF THE
TREATMENT AND FAST
RECOVERY TIMES

PATHOLOGIES

The following pathological conditions can be treated with **Plasma 4.0**:

TREATMENT OF NON- INVASIVE BLEPHAROPLASTY

upper eyelid dermatochalasis, xanthelasma

REMOVAL OF BENIGN NEOPLASMS

pendulous fibroids, warts, genital warts, exophytic lesions, cherry angioma, dermal nevi, seborrheic keratosis, sebaceous, cysts

SCAR REVISION

ACNE SCAR HEALING THERAPY

IMPERFECTIONS

Plasma 4.0 is also a **medical device suitable for aesthetic medicine activities for the high level of precision in the performance** of the treatment and fast recovery times treatment of following imperfections* and other unwanted skin conditions:

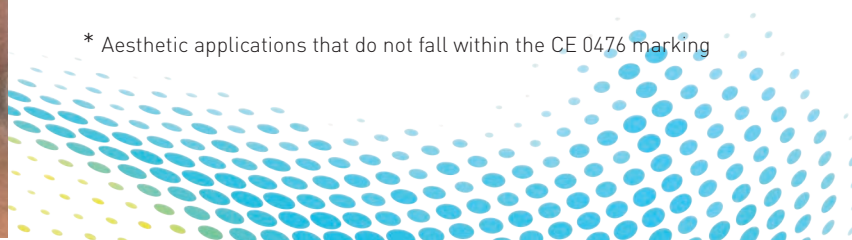
TREATMENT OF NON-INVASIVE BLEPHAROPLASTY

eyelid skin laxity*

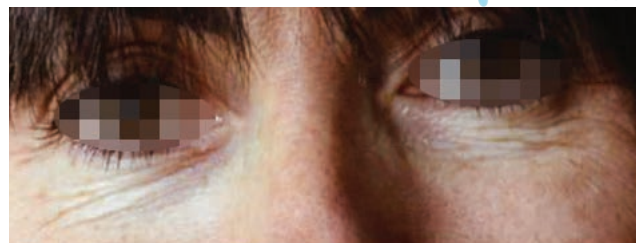
REVISION OF SCARS FROM PHOTOEXPOSURE AND PHOTOAGING*

TREATMENT OF RHYTIDOSIS wrinkles of the skin*

* Aesthetic applications that do not fall within the CE 0476 marking

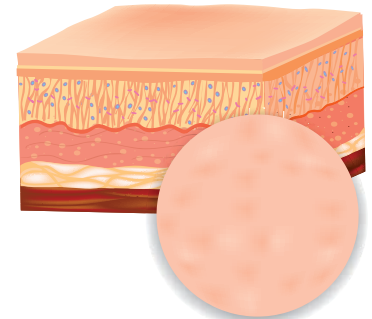
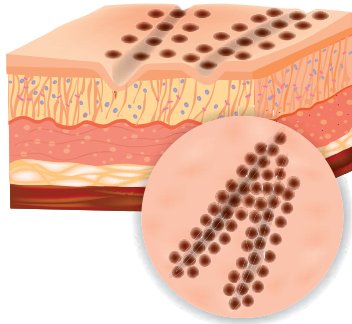


RESULTS



RELIABLE PERFORMING SAFE

CORRECTS SKIN IMPERFECTIONS
IN A SAFE AND FAST WAY
STIMULATING THE NATURAL
REGENERATION OF THE DERMIS.



OPERATING MODES

ONLY 5 STEPS SEPARATE
YOUR PATIENTS FROM
THEIR DESIRES

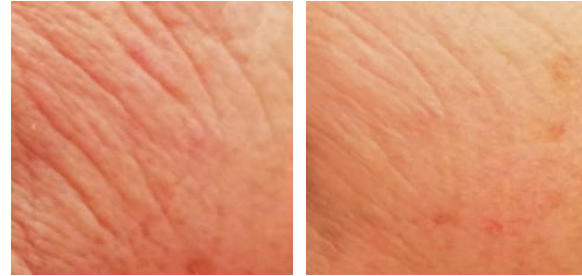
- STEP 1: remove make-up and disinfect the skin;
- STEP 2: clean with marsiglia soap and apply (if necessary) the anesthetic cream to the area that is going to be treated;
- STEP 3: start treatment with **Plasma 4.0**;
- STEP 4: during the treatment always keep the needle at the right distance;
- STEP 5: after the treatment disinfect the skin.

METHOD

Thanks to this system, the doctor works without ever touching the imperfection. The device, in fact delivers RF alternating current, the point-like needle on one side and the skin on the other constitute the two electrodes, while the air between the two acts as a medium of separation. In this way it is possible to supply the treated tissue with energy minimizing the thermal side effects.

The voltaic arc produced and visible to the naked eye, in fact, causes rapid heating of the skin with perfectly controlled tissue ablation and minimized collateral thermal damage. The technology used therefore allows an effective, minimally invasive and minimally painful treatment despite the sensitivity of the treated areas.





PLASMA 4.0 AND SKIN AGING

One of the most evident symptoms of skin aging is wrinkles: small folds on the surface of the skin caused by the advancing age but not only. The first wrinkles appear, in fact, as a consequence of facial expressions and increase or worsen with smoking, stress dehydration, the sun and drugs, but also because of one's genetic code.

Due to aging the skin becomes thin, drier and less elastic. Furthermore, over time the skin loses its natural ability to protect itself. The first wrinkles usually appear on the parts most exposed to the sun: hands, face and neck.

For an anti-aging effect you can rely on Plasma 4.0, the non-invasive and minimally painful treatment efficient in eliminating and/or reducing wrinkles and the natural aging of the skin.

SYNERGIES: PLASMA 4.0 AND FILLER

For a fresher, radiant and younger skin, the treatment with Plasma 4.0 can be associated with the application of bio-revitalizers, bionucleotides and dynamic fillers.

Thanks to the synergy with dynamic fillers, in addition to rejuvenation (soft restoration), a harmonious redefinition of the volumes and contours of the face is also obtained.

PLASMA 4.0 VS. COMPETITORS

- + EFFECTIVE
- + FAST IN TREATMENT TIMES
- + PRECISE
- + FAST IN POST-TREATMENT

THE BENEFITS OF PLASMA 4.0:

- > THE SCALPEL IS NOT USED;
- > NON-INVASIVE, RAPID AND PAINLESS TREATMENTS;
- > IN CASES OF NEOPLASMS, A SINGLE SESSION TO RESOLVE THE IMPERFECTION; OR A FEW RECALL SESSIONS TO MAINTAIN THE DESIRED EFFECT;
- > OPERATIONS WITHOUT ANESTHESIA, NO INCISIONS OR STITCHES, NO BLEEDING;
- > VISIBLE RESULTS AFTER THE FIRST SESSION AND SHORT RECOVERY TIMES. PATIENTS CAN RESUME LIFE NORMALLY AFTER A FEW HOURS;
- > SAFETY: DIRECT CONTACT WITH THE SKIN IS NOT NECESSARY, THERMAL SIDE EFFECTS ARE MINIMIZED;
- > MORE AFFORDABLE PRICES THAN COSMETIC SURGERY.



Notified Body No. 0476



TECHNICAL SPECIFICATIONS

Power supply	rechargeable battery
Batteries	3
Type of batteries	3,7V 2600mA, mod. ICR 18650 – 26F - Compliance IEC 62133
Exit stage	radiofrequency
Frequency	53 kHz (Wh rating 9,62 Wh x 3 battery)
RF levels	Adjustable from 0% to around 100%
Power IN	≈28 W (Wh rating 9,62 Wh x 3 battery)
Dimensions	225 x 45 x 35 mm
Weight	500 gr
Classification EN 60601-1	Device powered by source internal electrical system type BF
IP PROTECTION	IP 20
Operating conditions	Temperature -10°C - +35°C Humidity from 0 to 85% without condensation Atmospheric pressure from 600 to 1060 hPa
Conditions storage and transportation	Temperature -10°C - +35°C Humidity from 0 to 85% without condensation Atmospheric pressure from 600 to 1060 hPa
Compliance	Directive 93/42 e s.m.i.

CERTIFICATIONS



Reg. Number	MED 3190	Revision	0
Issue Number	2020-01-13	Issue Date	2020-01-13
Form Number		Valid From	2020-01-13
Subtotal	2024-06-26	Issue Validity	2020-01-13
Valid until		Last Change Date	

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CERTIFICATE

Certificato CE del Sistema di Garanzia della Qualità
EC Quality Assurance System Certificate

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema completo di garanzia di Qualità dell'Organizzazione ha erfüllt alle, on the basis of the audit carried out, the full Quality Assurance System of the Organization.

CESARE QUARANTA S.r.l.
Via Legnano, 3
10023 Chieri, TO, Italia

in conformità ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato al punto 4, attuale in Italia con Digi. 48 del 19/10/2024 e successive modifiche ed integrazioni per le seguenti famiglie di Dispositivi Medici e in compliance with the applicable requirements of 93/42/EEC Directive as amended. Annex 4, subpoint point 4, introduced in Italy by Digi. 48 of 19/10/2024 as amended for the following Medical Devices.

Dispositivo di plasma

Electron Beam S.p.A.
Via Legnano, 3
10023 Chieri, TO, Italia

CE

Organismo Notificatore n. 3476
Notified Body no. 3476



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CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed as the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices

Tipologia / Structural Device:
Dispositivo di plasma

Classe di rischio / Risk class:
II

Codice NANDO / NANDO code:
MD 1194, MED 7910

Modello / Model:
PLASMA 4.0, Plasmatouch, Neolith

La foto contenuta nel campo, relativa ai modelli certificati, è disponibile presso il sito Internet della: Per complete list of the valid models see the certification website or available at the Contact Data. For models Certificate is available in English. The technical sheet of the Contact Data and a valid one per the language of the applicant must be submitted together to the Registrar. The Certificate is subject to the Contact Data requirements and it is available for the other languages. The technical sheet is an integral part of the Certificate. For technical sheet see the complete part of the Certificate.

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PLASMA 4.0
IS A CERTIFIED
MEDICAL DEVICE,
PRODUCED IN ITALY,
BY CESARE QUARANTA SRL,
ISO9001:2015 AND
ISO13485:2016
CERTIFIED COMPANY

TECHNOLOGY
OF EXCELLENCE
MADE IN ITALY



CESARE
QUARANTA



Reg. Number	8771 - A	Revision	2021-05-14
Issue Date	2012-04-27	Last Change Date	2021-05-14
Valid From	2024-04-26	Valid Until	19 - 29
Previous Issue No.	2021-04-26		

CERTIFICATE

Quality Management System Certificate
ISO 9001:2015

We certify that the Quality Management System of the Organization:

CESARE QUARANTA S.r.l.
Via Legnano, 3 10023 Chieri (TO) - Italia

is in compliance with the standard UNI-EN ISO 9001:2015 for the following product(s):

Design, manufacture, service and placing on the market of electromedical devices for dermatology and aesthetic medicine
Design, manufacture, service and placing on the market of electronic equipment for the aesthetic sector.
Marketing and sale of cosmetic products.

Chief Operating Officer
Germanso Battisti

The membership of this certification is subject to annual surveillance and dependent on the observance of the Contact Data contractual requirements.

This certificate is composed of 3 pages.

Electron Beam S.p.A.
Via Legnano, 3
10023 Chieri, TO, Italia

CE

Organismo Notificatore n. 3476
Notified Body no. 3476



Reg. Number	8771 - A	Revision	2021-05-14
Issue Date	2012-04-27	Last Change Date	2021-05-14
Valid From	2024-04-26	Valid Until	19 - 29
Previous Issue No.	2021-04-26		

CERTIFICATE

Quality Management System Certificate
ISO 13485:2016

We certify that the Quality Management System of the Organization:

CESARE QUARANTA S.r.l.
Via Legnano, 3 10023 Chieri (TO) - Italia

is in compliance with the standard UNI-EN ISO 13485:2016 for the following product(s):

Design, manufacture service and placing on the market of electromedical devices for dermatology and aesthetic medicine

Chief Operating Officer
Germanso Battisti

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PLASMA 4.0: MOOIBR01, rev.3 del 01/06/2021
The information contained in this document is intended for healthcare professionals and / or medical professionals.


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OF EXCELLENCE
MADE IN ITALY



C E S A R E
Q U A R A N T A

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