CERTIFICATO CE

Certificato n. 1604/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

HIGH TECHNOLOGY PRODUCTS, SLU

08005 BARCELONA - Passatge Masoliver 24-28 (ESP) - Spain

mantiene nello stabilimento di:

08005 BARCELONA - Passatge Masoliver 24-28 (ESP) - Spain

08915 BADALONA - Plaza del Vapor, 2, P.I. Les Guixeres (ESP) - Spain

un sistema qualità che assicura la conformità dei seguenti prodotti:

Apparecchi per l'applicazione controllata del freddo ad uso medico

Laser a diodi per rimozione delle vene varicose, per epilazione nel trattamento di pseudofollicolite e dell'irsutismo e per il trattamento delle lesioni pigmentate e dell'acne patologica

Modd. come da documento allegato "ANNEX TO EC CERTIFICATE" rev. 1 del 18/07/2019; valido solo se provvisto del timbro IMQ

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Riferimento pratiche IMQ:

10AM00102; 10AO00071; DM17-0019229-01; DM18-0025304-01; DM18-0022289-01; DM18-0029072-01; DM18-0033393-01; DM18-0032531-01; DM19-0037198-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il:	2013-05-29
Data aggiornamento:	2019-08-01
Sostituisce:	2019-02-04
Data scadenza:	2023-05-17

IMQ

EC CERTIFICATE

Certificate No 1604/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

HIGH TECHNOLOGY PRODUCTS, SLU

08005 BARCELONA - Passatge Masoliver 24-28 (ESP) - Spain

manages in the factory of:

08005 BARCELONA - Passatge Masoliver 24-28 (ESP) - Spain

08915 BADALONA - Plaza del Vapor, 2, P.I. Les Guixeres (ESP) - Spain

a quality assurance system ensuring the conformity of the following products:

Controlled cooling application equipment for medical use

Diode laser equipment for removal of varicose veins, for hair removal in the treatment of pseudofollicolitis and hirsutism and for the treatment of pigmented lesions and pathological acne

Type ref. As to annexed document "ANNEX TO EC CERTIFICATE" rev. 1 dated 2019/07/18; valid only if provided with IMQ stamp.

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

10AM00102; 10AO00071; DM17-0019229-01; DM18-0025304-01; DM18-0022289-01; DM18-0029072-01; DM18-0033393-01; DM18-0032531-01; DM19-0037198-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date:	2013-05-29
Updated:	2019-08-01
Substitution Date:	2019-02-04
Expiry Date:	2023-05-17

IMQ

ANNEX TO:

EC CERTIFICATE

Certificate No 1604/MDD

Full Quality Assurance System Approval Certificate

HIGH TECHNOLOGY PRODUCTS, SLU
Passatge Masoliver 24-28 – 08005 –
Barcelona, Spain

Manages the following manufacturing sites for the listed Medical Devices:

DOCUMENT NAME	ANNEX TO **EC CERTIFICATE**
REVIEW	Rev.1
DATE OF ISSUE	18 / 07 /2019
MEDICAL DEVICES INFORMATION	**Controlled cooling application equipment for medical use** Type ref. COOLTECHNOLOGY; CRYOTECHNOLOGY Trade mark COCOON MEDICAL; COOLTECH **Diode laser equipment for removal of varicose veins, for hair removal in the treatment of pseudofolliculitis and hirsutism and for the treatment of pigmented lesions and pathological acne** Type ref. Elysion; Primelase Trade mark COCOON MEDICAL
MANUFACTURING SITES	**COCOON MEDICAL INTERNATIONAL Ltd.** Tax/Legal address: KATIPAN ANDREEV, 25 – 1000 – SOFIA (BULGARIA) Facility address: PORUCHIK N. BONCHEV Str., 6 – 1528 – SOFIA (BULGARIA)
OWNER	Jose Antonio Sánchez Jaime CEO and single owner
MD CLASSIFICATION (93/42/EEC and its revised version)	Type ref. COOLTECHNOLOGY; CRYOTECHNOLOGY **(class IIa)** Type ref. Elysion; Primelase **(class IIb)**
NOTIFIED BODY	**IMQ S.p.A.** under number 0051
EC CERTIFICATE EXAMINATION	Annex II, excluding section 4

2019-08-01

HIGH TECHNOLOGY PRODUCTS, SLU

Passatge Masoliver, 24-28
08005, Barcelona, Spain
Tel. +34 934 588 566
www.cocoonmedical.com