



CERTIFICATO CE

Certificato n. 2084/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:

Osteophoenix, S.L.

48002 Bilbao (Vizcaya) - C/ Bentazarra, 4, 5B (ESP) - Spain

mantiene nello stabilimento di:

48950 Erandio (Vizcaya) - P.I. Urazandi, C/ Portubidea 1, Nave A1 (ESP) - Spain

un sistema qualità che assicura la conformità dei seguenti prodotti:

Membrane di titanio ad uso dentale

Modd. FM2535; FS1825

Marca OSTEOPHOENIX

Dispositivi di fissazione per le membrane di rigenerazione ossea guidata e per le guide chirurgiche ad uso dentale

Modd. Come da documento "EC CERTIFICATE ANNEX A - DEVICES LIST - TECH 2- Rev. 3 dated 04/02/2020"; valido solo se provvisto del timbro IMQ.

Marca OSTEOPHOENIX

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:

DM19-0036850-01.

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: 2020-04-02

IMQ

Data scadenza: 2024-05-26



EC CERTIFICATE

Certificate No 2084/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:

Osteophoenix, S.L.

48002 Bilbao (Vizcaya) - C/ Bentazarra, 4, 5B (ESP) - Spain

manages in the factory of:

48950 Erandio (Vizcaya) - P.I. Urazandi, C/ Portubidea 1, Nave A1 (ESP) - Spain

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

Titanium foils for dental use

Type ref. FM2535; FS1825
Trade mark OSTEOPHOENIX

Fixation devices for guided bone regeneration membranes and surgical guides for dental use

Type ref. As to document "EC CERTIFICATE ANNEX A - DEVICES LIST - TECH 2- Rev. 3 dated 04/02/2020";
valid only if provided with IMQ stamp.
Trade mark OSTEOPHOENIX

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:

DM19-0036850-01.

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: 2020-04-02

IMQ

Expiry Date: 2024-05-26

EC CERTIFICATE ANNEX A - DEVICES LIST

TECH 2- Rev. 3 dated 04/02/2020

PRODUCT CATEGORY:	FIXATION DEVICES FOR GUIDED BONE REGENERATION MEMBRANES AND SURGICAL GUIDES																																			
TYPE REF:	<table border="1"> <thead> <tr> <th data-bbox="475 640 564 672">NAME</th> <th data-bbox="1150 640 1310 672">REFERENCE</th> </tr> </thead> <tbody> <tr> <td data-bbox="475 701 1018 732">Osteosynthesis screw ø 1.5 long. 5 mm</td> <td data-bbox="1150 701 1230 732">T1505</td> </tr> <tr> <td data-bbox="475 761 1018 792">Osteosynthesis screw ø 1.5 long. 7 mm</td> <td data-bbox="1150 761 1230 792">T1507</td> </tr> <tr> <td data-bbox="475 822 1018 853">Osteosynthesis screw ø 1.5 long. 9 mm</td> <td data-bbox="1150 822 1230 853">T1509</td> </tr> <tr> <td data-bbox="475 882 991 913">Osteosynthesis screw ø 2 long. 5 mm</td> <td data-bbox="1150 882 1230 913">T2005</td> </tr> <tr> <td data-bbox="475 943 991 974">Osteosynthesis screw ø 2 long. 7 mm</td> <td data-bbox="1150 943 1230 974">T2007</td> </tr> <tr> <td data-bbox="475 1003 991 1034">Osteosynthesis screw ø 2 long. 9 mm</td> <td data-bbox="1150 1003 1230 1034">T2009</td> </tr> <tr> <td data-bbox="475 1064 1018 1095">Osteosynthesis screw ø 2.3 long. 5 mm</td> <td data-bbox="1150 1064 1230 1095">T2305</td> </tr> <tr> <td data-bbox="475 1124 1018 1155">Osteosynthesis screw ø 2.3 long. 7 mm</td> <td data-bbox="1150 1124 1230 1155">T2307</td> </tr> <tr> <td data-bbox="475 1184 1018 1216">Osteosynthesis screw ø 2.3 long. 9 mm</td> <td data-bbox="1150 1184 1230 1216">T2309</td> </tr> <tr> <td data-bbox="475 1245 783 1276">Screw Foil long. 6 mm</td> <td data-bbox="1150 1245 1214 1276">TF06</td> </tr> <tr> <td data-bbox="475 1305 783 1337">Screw Foil long. 8 mm</td> <td data-bbox="1150 1305 1214 1337">TF08</td> </tr> <tr> <td data-bbox="475 1366 810 1397">Dental tack long. 3 mm</td> <td data-bbox="1150 1366 1225 1397">CH03</td> </tr> <tr> <td data-bbox="475 1426 810 1458">Dental tack long. 5 mm</td> <td data-bbox="1150 1426 1225 1458">CH05</td> </tr> <tr> <td data-bbox="475 1487 735 1518">Pin ø 1 long. 4 mm</td> <td data-bbox="1150 1487 1230 1518">P0104</td> </tr> <tr> <td data-bbox="475 1547 735 1579">Pin ø 1 long. 5 mm</td> <td data-bbox="1150 1547 1230 1579">P0105</td> </tr> <tr> <td data-bbox="475 1608 730 1639">Pin ø 1 long. 6mm</td> <td data-bbox="1150 1608 1230 1639">P0106</td> </tr> </tbody> </table>	NAME	REFERENCE	Osteosynthesis screw ø 1.5 long. 5 mm	T1505	Osteosynthesis screw ø 1.5 long. 7 mm	T1507	Osteosynthesis screw ø 1.5 long. 9 mm	T1509	Osteosynthesis screw ø 2 long. 5 mm	T2005	Osteosynthesis screw ø 2 long. 7 mm	T2007	Osteosynthesis screw ø 2 long. 9 mm	T2009	Osteosynthesis screw ø 2.3 long. 5 mm	T2305	Osteosynthesis screw ø 2.3 long. 7 mm	T2307	Osteosynthesis screw ø 2.3 long. 9 mm	T2309	Screw Foil long. 6 mm	TF06	Screw Foil long. 8 mm	TF08	Dental tack long. 3 mm	CH03	Dental tack long. 5 mm	CH05	Pin ø 1 long. 4 mm	P0104	Pin ø 1 long. 5 mm	P0105	Pin ø 1 long. 6mm	P0106	
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