MOD. 1475A / 2

EC CERTIFICATE

Certificate No 1976/MDD

Production Quality Assurance System Approval Certificate

On the basis of our assessment carried out according to Annex V, section 3 and considering the Annex VII, section 5 of the Directive 93/42/EEC and its revised version, we hereby certify that:

CERACARTA SPA

47122 FORLI' (FC) - VIA SECONDO CASADEI 14 Z.I. VILLA SELVA (ITA) - Italy

manages in the factories of:

47122 FORLI' (FC) - VIA SECONDO CASADEI 14 Z.I. VILLA SELVA (ITA) - Italy

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

Electromedical recording chart paper

Type ref. as to annexed document "ELENCO CARTE DIAGRAMMATE CLASSE I F.M. REV.15 - 16/10/2017"; valid only if provided with IMQ stamp.
Trade mark Ceracarta

with the relevant metrological requirements of the aforementioned directive (as far as all the manufacturing stage is concerned) and it is subject to surveillance as specified in section 4 of Annex V.

Reference to IMQ files Nos:
DM17-0017248-01.

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: 2017-11-18

Expiry Date: 2022-11-17

IMQ cosign

IMQ CSQ
ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".

This is a translation of the Italian text, which prevails in case of doubts

CE ATITIKIMO DEKLARACIJA

Sertifikato Nr. 1 976 / MDD

KOKYBĖS VADYBOS UŽTIKRINIMO PAŽYMĖJIMAS

Remiantis įvertinimu, atliktu pagal V priedo 3 skirsnį ir įvertinę Direktyvos 93/42 / EEB VII priedo 5 skirsnį, šiuo dokumentu patvirtiname, kad įmonė:

CERACARTA SPA

47122 FORLI '(FC) - VIA SECONDO CASADEI 14 Z.I. V ILLA SELVA (ITA) - Italija
valdo gamyklose:
47122 FORLI '(FC) - VIA SECONDO CASADEI 14 Z.I. VILLA SELVA (ITA) - Italija
kokybės užtikrinimo sistema, užtikrinanti šių gaminių atitiktį.

Elektromedicininis registracinis popierius

Ref. kaip pridedamas dokumentas „ELENCO CARTE DIAGRAMMATE CLASSE I F.M REV.15 - 2017-10-16“; galioja tik pasirašius IMQ. Prekių ženklas Ceracarta

su minėtos direktyvos atitinkamais metrologiniais reikalavimais (kiek tai susiję su visu gamybos etapu) ir jai taikoma priežiūra, kaip nurodyta V priedo 4 skirsnyje.

Nuoroda į IMQ failus:
DM17-0017248-01

Šį patvirtinimo sertifikatą išleido IMQ S.p.A. kaip Direktyvos 93/42 / EEB ir jos papildytos versijos notifikuotoji įstaiga.

Notifikuota įstaiga, notifikuota Europos komisijai numeriu: 0051

Data: 2017-11-18 IMQ parašas

Galioja iki 2022-11-17 IMQ logotipas