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DICHIARAZIONE DI CONFORMITA / DECLARATION DE CONFORMITE DECLARATION OF CONFORMITY / KONFORMITÄTSERKLÄRUNG

Nome e indirizzo della ditta
Nom et adresse de l'entreprise
Name und Adresse der Firma
Company Name and Address

LUMED srl
Via Staffora 18/9 – 20090 Opera (MI)
ITALIA

Dichiariamo sotto nostra responsabilità che / Nous déclarons sous notre propre responsabilité que / Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that

il Dispositivo Medico
le Dispositif Médical
das MedizinProdukt
the Medical Device

Cavi paziente per ECG
Câbles patient pour ECG / ECG Patient Cables / EKG Pazientkabel

Codice/ref/ref/Artikelnr.

EEHLnn,EEHLnn-nn,EEHLnnXL,EEHLnn/CLIP,
EE203SK-xxn,EE203SK-APFH,EE100xxx-nnn,
EE100xxxx-nnn,EE103BK-TRIM,EE103BK-TC
EE103BK-TC16,EE103BK-WAM,EE100NRI-NV200
EP-MGA00000

di classe / de la classe / der Klasse / of class

I
secondo l'allegato IX della direttiva 93/42/CEE
selon l'annexe IX de la directive 93/42/CEE
Nach Anhang IX der Richtlinie 93/42/EWG
according to annex IX of directive 93/42/EEC

soddisfa tutte le disposizioni della direttiva 93/42/CEE (modificata da 2007/47/CEE) che lo riguardano / remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE (modifie par 2007/47/CEE) qui le concernent / allen Anforderungen der Medizinprodukte-Richtlinie 93/42/EWG (modifizierte mit 2007/47/CEE) entspricht, die anwendbar sind / meets all the provisions of the directive 93/42/EEC (modified by 2007/47/EEC) which apply to it.

Norme armonizzate o nazionali applicate, altri documenti normativi applicati
Normes harmonisées, normes nationales et autres documents normatifs appliqués
Angewandte harmonisierte Normen, nationale Normen oder andere normative Dokumente
Applied harmonised standards, national standards or other normative documents

EN ISO 14971:2012 Application of risk management to Medical Devices

UNI CEI EN ISO 15223-1 :2017 Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

EN ISO 10993-10:2013 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

Procedimento di valutazione della conformità
Procédure d'évaluation de la conformité
Konformitätsbewertungsverfahren
Conformity assessment procedure

ANNEX V of Directive 93/42/CEE

Organo incaricato della valutazione della conformità
Organe resp. de l'évaluat. de la conformité
Konformitätsbewertungsstelle
Notified Body

Kiwa Cermet Italia srl, Notified Body No. 0476

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Opera 30/03/20
Luogo, data / Lieu, date / Ort, Datum / Place, date

.....
Fabio Santamarina (Legal Representative)
Nome e funzione / Nom et fonction /
Name und Funktion / Name and Role