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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

**Electrocardiografi / Électrocardiographes / EKG-Geräten / Electrocardiographs**

codice/ref/ref/Artikelnr.

EP-LU30001 (EUROECG 3view)
EP-LU30002 (EUROECG 6view)
EP-LU30003 (EUROECG 12view)

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

**IIa**
secondo l'allegato IX della direttiva 93/24/CEE
selon l'annexe IX de la directive 93/42/CEE
Nach Anhang IX der Richtlinie 93/43/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

**ISO 14971:2012 Application of risk management to Medical Devices**
**UNI CEI EN ISO 15223-1:2017Symbols to be used with medical device labels, labelling and information to be supplied**

**EN60601-1:2006 - Medical electrical equipment --Part1: General requirements for basic safety and essential performance IEC 60601-1:200**

**EN 60601-1-2:2007 Medical electrical equipment -- Part 1-2: - Collateral standard: Electromagnetic compatibility - Requirements and testsIEC 60601-1-2:2007 (Modified)**

**EN 60601-1-6:2007 Medical electrical equipment -- Part 1-6 Collateral Standard: Usability IEC 60601-1-6:2006**

**EN 60601-2-25:1995+A1:199 - Medical electrical equipment -- Part 2-25: Particular requirements for the safety of electrocardiographs IEC 60601-2-25:1993+A1:1999**

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

**ANNEX II**
**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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Digitally signed by Botnaru Tatiana
Date: 2020.07.30 12:55:21 EEST
Reason: MoldSign Signature
Location: Moldova

**Opera, 20/04/19**
Luogo, data / Lieu, date / Ort, Datum / Place, date

.....

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