

DECLARATION OF CONFORMITY

We declare under our sole responsibility that

the medical device

Wero Lux K-10 white, 4m stretched

of class

Class 1, unsterile

Annex IX of medical device directive 93/42
EEC, Rule1

Distributed by

Name and address of the firm

FRA Production S.p.A.
Via delle Poste n. 16
I-14010 Dusino San Michele (AT)
Italy

meets all the provisions of the directive 93/42/EEC which apply to it.

Applied harmonised standards, national
standards or other normative documents

– ISO 10993-1:2009
– ISO 15223:2000

Place, date

Rothrist, 7th September 2017

Name and function



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Felix Schönle, CEO