



DECLARATION OF CONFORMITY TO CE MARK

THE MANUFACTURER:

KW APPARECCHI SCIENTIFICI S.R.L.

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DECLARES THAT THE MODELS:

UDI-DI: 8057506150014 SERIES: Plasma and Stem Cells Thawer MODEL: WPFD 2/4

UDI-DI: 8057506150007 SERIES: Plasma and Stem Cells Thawer MODEL: WPFD 3/6

ARE COMPLIANT WITH THE FOLLOWING EUROPEAN COMMUNITY REGULATION:

- MEDICAL DEVICES 2017/745 - 05/04/2017
Class I
QMS ISO 13485:2016

ARE COMPLIANT WITH THE FOLLOWING COMMUNITY DIRECTIVES:

- ELECTROMAGNETIC COMPATIBILITY 2014/30/UE
- LOW VOLTAGE 2014/35/UE
- MACHINERY DIRECTIVE 2006/42/CE

ARE COMPLIANT WITH THE FOLLOWING TECHNICAL STANDARDS:

- SAFETY CEI EN 61010 – 1: 2010 / A1:2019
- ELECTROMAGNETIC COMPATIBILITY CEI EN 61326 – 1: 2013

Ing. Fabiani Stefano
President and C.E.O.



Monteriggioni, 16/03/2023