



**APPARECCHI
SCIENTIFICI**

DECLARATION OF CONFORMITY TO CE MARK



MANUFACTURER:

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DECLARES THAT:

UDI-DI: 8057506150014
SERIES: Plasma and stem cell thawer
MODEL: WPFD 2/4

UDI-DI: 8057506150007
SERIES: Plasma and stem cell thawer
MODEL: WPFD 3/6

ARE COMPLIANT WITH THE FOLLOWING EUROPEAN 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

Signature
Ing. Fabiani Stefano
General manager

Monteriggioni, 14/04/2022



ISO 9001:2015 ISO 13485:2016 OHSAS 18001:2007 ISO 14001:2015