



EC DECLARATION OF CONFORMITY

Manufacturer: BUNSEN S.A.

Address: C/Tokio, 2 Pol. Industrial Wells.

DECLARE THAT THE PRODUCT: High speed centrifuge

TRADEMARK: BUNSEN

MODEL: HEMO REF.1461

IS IN ACCORDANCE WITH THE REGULATIONS OF THE EU DIRECTIVES:

Directive for low voltage 2014/35/EC

Directive electromagnetic compatibility 2014/30/EC

Directive 98/79/EC-in vitro diagnostic medical devices:

Product non classified to list A or B and not for self-testing.

APPLIED HARMONIZED STANDARDS:

EN 61010-1:2010

EN 61010-2-020:2006

EN 980:2008

EN ISO 13485:2012

EN ISO 13485:2012/AC:20

EN 13612:2006

EN 13612:20A2/AC:2002

EN ISO 14971:2012

EN ISO 18113-1:2011

EN ISO 18113-3:2011

EN 61325-2-6:2006

EN 61010-2-101:2002

EN 62304:2006

EN 62304:2006/AC:2008

EN 62366:2008

YEAR OF CE MARKING: 2017.

PLACE AND DATE: Humanes de Madrid, September 5, 2017

Signed: Miguel Ángel Martín Jimenez
Technical director