DECLARATION OF INCORPORATION

In respect to the following Directives

EMC Directive Low Voltage Directive WEEE & RoHS3 Directive 2014/30/EU 2014/35/EU

2002/96/EC & EU 2015/863

the manufacturer



Thermo CRS Ltd Laboratory Automation 5250 Mainway Burlington, Ontario Canada L7L 5Z1

Phone: (905) 332-2000 Fax: (905) 332-1114

hereby declares that the product(s) Product Name

OrbitorRS2 OrbitorRS2 BenchTrak F02036 F01848 - F01855 F01856 - F01863

On-Bench (800mm - 3600mm)

System Components (optional / configurable) Hotel mounting platforms, Random Access Hotels, and Hotel Stacks

Guard panels - fixed and interlocked

In-Bench (800mm - 3600mm)

conform(s) to the following

standards or

other normative

EM Emissions

CISPR11:2009 + A1:2010 / EN 55011:2009 +A1:2010, Class A, Group 1 ISM Equipment

FCC Part 15, Subpart B, Class A

EM Immunity

EN61326-1:2013

CISPR11:2009+A1:2010/EN55011:2009+A1:2010, Class A

Electrical safety of

CAN/CSA-C22.2 No. 61010-1-12, 3rd ed., CAN/CSA-C22.2 No. 61010-2-081:15

UL61010-1, 3rd ed., UL61010-2-081, 2nd ed.

documents equipment for measurement, control, and laboratory use

Machine Safety Machine Safety

IEC61010-1:2010, IEC61010-2-081:2015

EN ISO 13849-1:2006 (PL=c, PFH=1.14E-6, using the MiniHub)

TS15066:2016, Robots and Robotic Devices - collaborative robots, section 5.5.4 Power and force limiting

Environmental (RoHS3)

This equipment, to the best of our knowledge, complies with European Directive EU 2015/863 on the Restriction of Hazardous Substances (RoHS3). Thermo CRS bases its evaluation on information provided by third parties and has taken and continues to take reasonable steps to provide accurate information. Thermo CRS has not conducted destructive testing or chemical

analysis on the incoming materials.

China RoHS

Conforms to standard GB/T26572. Refer to the following website for the information table. http://www.thermofisher.com/us/en/home/technical-resources/rohs-certificates.html

Collaborative Operation

The OrbitorRS2 is safe to use at all speeds when the workspace is correctly designed. When operating with a BenchTrak, the OrbitorRS2 will operate in "collaborative mode". This mode restricts operation of the unit to a lower speed which meets the requirements of the power and force limits of the TS15066 standard. Even at the lower speed, additional measure (safeguards, PPE, operating procedures) may be required to adequately reduce the risk of injury to the operator due to hazards of the application, the biology/chemistry, or the instruments. To operate at a higher speed, the OrbitorRS2 BenchTrak must be connected to a MiniHub or an E-Stop hub.

The use of impact resistant eye-protection is highly recommended at all times when operating the OrbitorRS2.

Partly Completed

Although the OrbitorRS2 BenchTrak is a completed and functional product on its own, it's considered "partly completed" machinery by the Machinery Directive, and must not be put into service until the final "system" into which they are integrated, has been declared in conformity with the ESHR (Essential Health and Safety Requirements) of the Machinery Directive. Additional safety measures (i.e. safeguarding) may be required to bring it into compliance with the Directive. This is determined by a Safety Risk Assessment of the integrated system.

Supplementary Information

The Safety chapters of the "OrbitorRS2 User Guide" and the "BenchTrak User Guide" must be reviewed before the product is put into service. The guides contain important safety information about residual hazards.

The OrbitorRS2 and OrbitorRS2 BenchTrak are designed for the purpose of moving microtitre plates that conform to the SBS standard, between instruments. A risk analysis specific to the materials being handled in the customer's application must be done, as it may dictate the need for mitigation measures (i.e. ventilation, guarding, personal protective equipment, etc.) to reduce the risk of injury to the operator.

When and Where Issued:

Dec 18, 2020 Burlington, Ontario, Canada Contact established in the Community authorized to compile the technical file or the relevant technical documents

Hansjoerg Haas

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• Revision History

Rev.	Date	Comments
0.	Nov 29, 2017	GED; Created; preliminary
1.	Mar 18, 2019	RF: Changed CE Authorized Representative due to Brexit
2.	Dec 18, 2020	SV: updated RoHS3 information & Signatory