Memorandum

Date: April 21, 2022

To: Cleanroom_TSX23-50cf_TFS_r20220421.pdf

From: Kayla Sanders

Regarding: Regarding clean room test unit representation, version 4

We, Thermo Fisher Scientific Asheville LLC, have conducted an internal evaluation of the product listed below, and selected representative samples for Third Party Environmental testing, as specified below and attached in the official Agency report, titled “Clean Room Evaluation Report”. The report indicates the representation for the entire product family, described by Engineering name as “TSX 2330 -30 Freezer”. These were covered by UL Project Number 18849-010AA. We hereby declare that the models listed below are in conformity by means of engineering justification of product family grouping and testing of worst-case family representation.

The current TSX HPLRF portfolio covered by this declaration consists of four different unit sizes and four different operating temperatures. The temperatures of the units are +4ºC, +5ºC, -20ºC, and -30ºC which have no significant design differences that impact cleanroom compatibility. The sizes of the units are based on the nominal internal capacity of the units and include: 23 cu ft, 30 cu ft, 45 cu ft, and 50 cu ft. Five different voltage options are available, creating a matrix of comparable models.

With the guidance of UL, two considerations fed into the evaluation of these units: moving parts that may create particulate, and the airflow of the unit which may drive that particulate outside the unit. The only moving part outside of the refrigerated compartment (an enclosed area) that interacts with the surrounding environment is a fan used for cooling. Air is pulled by a fan into the upper deck through the condenser and exits through vent holes in the top of the unit. The region that active airflow is present is called the Compressor Deck Area. The direction of airflow, fan size, and fan speeds are the same for all models. The different voltages do not change clean room compatibility since the airflow is the same.

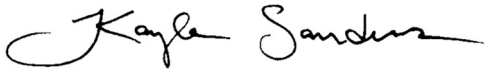
The 23 cu ft, 30 cu ft, 45 cu ft and 50 cu ft have an identical compressor deck size inside the housing of the unit. The selection of components and layout is similar among models. Cleanroom testing was performed on the TSX2330FD.

This unit was subjected to the testing of ISO 14644-14:2016. This part of the ISO 14644 series specifies a method to assess the suitability of equipment for use in cleanrooms and associated controlled environments, with respect only to airborne particle cleanliness as specified in ISO 14644-1.

Based on the results of the ISO 14644-14 testing of the TSX2330FD, the following TSX Series models are therefore declared by Thermo Fisher Scientific to be suitable, with respect to airborne particle cleanliness, for **ISO Class 6.0** (ISO EN 14644-1:2015 classification)**; In Operation; ≥0.1µm, ≥0.2µm, ≥0.3µm, ≥0.5µm, ≥1.0µm, ≥5.0µm** and EU GMP **Grade A** compatible with appropriate pre-install preparation.

Thermo Fisher Scientific Models

23 cu ft	TSX2304BA, TSX2305GA, TSX2305CA, TSX2305PA, TSX2305SA, TSX2304BD, TSX2305GD, TSX2305CD, TSX2305PD, TSX2305SD, TSX2304BV, TSX2305GV, TSX2305CV, TSX2305PV, TSX2305SV, TSX2304BY, TSX2305GY, TSX2305CY, TSX2305PY, TSX2305SY, TSX2304BZ, TSX2305GZ, TSX2305CZ, TSX2305PZ, TSX2305SZ, TSX2320EA, TSX2320FA, TSX2320ED, TSX2320FD, TSX2320EV, TSX2320FV, TSX2320EY, TSX2320FY, TSX2320EZ, TSX2320FZ, TSX2330FA, TSX2330LA, TSX2330FD, TSX2330LD, TSX2330FV, TSX2330LV, TSX2330FY, TSX2330LY, TSX2330FZ, TSX2330LZ,
30 cu ft	TSX3004BA, TSX3005GA, TSX3005CA, TSX3005PA, TSX3005SA, TSX3004BD, TSX3005GD, TSX3005CD, TSX3005PD, TSX3005SD, TSX3004BV, TSX3005GV, TSX3005CV, TSX3005PV, TSX3005SV, TSX3004BY, TSX3005GY, TSX3005CY, TSX3005PY, TSX3005SY, TSX3004BZ, TSX3005GZ, TSX3005CZ, TSX3005PZ, TSX3005SZ, TSX3020EA, TSX3020FA, TSX3020ED, TSX3020FD, TSX3020EV, TSX3020FV, TSX3020EY, TSX3020FY, TSX3020EZ, TSX3020FZ, TSX3030FA, TSX3030LA, TSX3030FD, TSX3030LD, TSX3030FV, TSX3030LV, TSX3030FY, TSX3030LY, TSX3030FZ, TSX3030LZ,
45 cu ft	TSX4505GA, TSX4505CA, TSX4505GD, TSX4505CD, TSX4505GV, TSX4505CV, TSX4505GY, TSX4505CY, TSX4505GZ, TSX4505CZ
50 cu ft	TSX5004BA, TSX5005GA, TSX5005CA, TSX5005PA, TSX5005SA, TSX5004BD, TSX5005GD, TSX5005CD, TSX5005PD, TSX5005SD, TSX5004BV, TSX5005GV, TSX5005CV, TSX5005PV, TSX5005SV, TSX5004BY, TSX5005GY, TSX5005CY, TSX5005PY, TSX5005SY, TSX5004BZ, TSX5005GZ, TSX5005CZ, TSX5005PZ, TSX5005SZ, TSX5030FA, TSX5030LA, TSX5030FD, TSX5030LD, TSX5030FV, TSX5030LV, TSX5030FY, TSX5030LY, TSX5030FZ, TSX5030LZ,



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Appendix A: Particle Counts

During testing, particle count was as follows (pulled from report).

RESULTS

The mean particle concentrations, upper confidence limit in the chamber and corresponding ISO Class ratings are summarized in Table 2.

TABLE 2

Particle Concentrations and Cleanroom Classification for Loaded Chamber

Description	Particle Size			
	≥ 0.1 µm	≥ 0.2 µm	≥ 0.3 µm	≥ 0.5 µm
Mean Concentration (#/ m^3)	234,473	9,039	2,518	890
Upper Confidence Limit	339,581	11,731	2,649	936
ISO Class	6.0	5.0	4.5	4.5

ISO 14644 -14 limits the determination of a device to no less than one Class number greater than the Class number of the environmental chamber used for the test. The calculated Class number of the chamber with the test appliance was greater than one ISO Class number above that of the empty chamber. Thus the appliance meets the criteria for an "operational" ISO Cleanroom Class 6.0 based on the calculated value.

An assessment including an agreed upon representative mode of operation, according to ISO 14644-14 showed that: the "TSX 2330 -30 Freezer" has cleanroom suitability for use within a cleanroom of ISO Class 6.0 (≥ 0.1 µm, ≥ 0.2 µm, ≥ 0.3 µm and ≥ 0.5 µm).

Additional measurements were collected during the test for the 1 and 5 µm particle size range. A summary of these measurements is included in the table below for informational purposes.

Empty Chamber

Description	1.0 µm	5.0 µm
Mean	12	1
Standard Deviation	69	5
Upper Confidence Limit	27	2

TSX 2330 -30 FREEZER Operational Mode

Description	1.0 µm	5.0 µm
Mean	125	4
Standard Deviation	88	30
Upper Confidence Limit	138	9

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Appendix B Classifications

The following table is pulled from the ISO 14644-1:2015 standard for Classification of Air Cleanliness by Particle Concentration.

Table 1 — ISO Classes of air cleanliness by particle concentration

ISO Class number (*N*)	Maximum allowable concentrations (particles/m^3) for particles equal to and greater than the considered sizes, shown below[a]					
	0,1 µm	0,2 µm	0,3 µm	0,5 µm	1 µm	5 µm
1	*10*[b]	d	d	d	d	e
2	100	*24*[b]	*10*[b]	d	d	e
3	1 000	237	102	*35*[b]	d	e
4	10 000	2 370	1 020	352	*83*[b]	e
5	100 000	23 700	10 200	3 520	832	d, e, f
6	1 000 000	237 000	102 000	35 200	8 320	293
7	c	c	c	352 000	83 200	2 930
8	c	c	c	3 520 000	832 000	29 300
9g	c	c	c	35 200 000	8 320 000	293 000

a All concentrations in the table are cumulative, e.g. for ISO Class 5, the 10 200 particles shown at 0,3 µm include all particles equal to and greater than this size.

b These concentrations will lead to large air sample volumes for classification. Sequential sampling procedure may be applied; see Annex D.

c Concentration limits are not applicable in this region of the table due to very high particle concentration.

d Sampling and statistical limitations for particles in low concentrations make classification inappropriate.

e Sample collection limitations for both particles in low concentrations and sizes greater than 1 µm make classification at this particle size inappropriate, due to potential particle losses in the sampling system.

f In order to specify this particle size in association with ISO Class 5, the macroparticle descriptor M may be adapted and used in conjunction with at least one other particle size. (See C.7.)

g This class is only applicable for the in-operation state.