

## ISO 14644 Cleanroom Certificate for Biohit Oyj Kajaani tip production

### Cleanroom criteria:

ISO 14644-1:2000. Cleanrooms and associated controlled environments: Classification of air cleanliness.

At rest: ISO 7, particle size 0,5 (352 000 pcs/m<sup>3</sup>) and 5,0 (2930 pcs/m<sup>3</sup>)

Operational: ISO 8, particle size 0,5 (3 520 000 pcs/m<sup>3</sup>) and 5,0 (29 300 pcs/m<sup>3</sup>)

### Test methods used:

Particle counts were taken with Met One 3423 particle counter programmed for 1 minute counts and 3 to 5 locations were measured per production cell (At rest). At operational stage 8 pcs of 1 minute measurements were taken from the critical location of each cell. Air volumes were measured with Swema 3000 Swa31 hot-wire anemometer underneath face surface of the filters. Air flow visualizations were performed with specific marker fog.

### Statement:

All production cells tested met the requirements for ISO 14644 class 7 (At rest) and class 8 (Operational) cleanroom.

The above information is stated per the "ISO 14644 Cleanroom certificate for Biohit Oyj. Kajaani, tip production", dated June 2<sup>nd</sup> 2010 and granted to Biohit Oyj by an ISO 9001 and DNV certified validation organization.

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