

DECLARATION OF CONFORMITY

BioCapt® Stainless Steel Microbial Impactor

BioCapt Microbial Impactor, component of the **MiniCapt® Mobile** Air Sampler System and of the **MiniCapt® remote** sampling system, has a physical and biological efficiency defined in compliance with ISO 14698-1 (Clean rooms and associated controller environments – Biocontamination control – Part 1: General principles and methods (ISO14698-1:2003)).

The original design incorporate a unique radial slit impactor consisting of twenty (20) slits, in a 316L stainless steel head, precision-cut by electrical discharge machining.

The airflow through the slits is laminar ensuring that bacteria, fungi, and other viable particles of interest are undamaged during sampling, resulting in a consistent physical and biological efficiency.

The conformity to the ISO 14698-1:2003 standard of the BioCapt impactor (at 25-50 LPM) is certified by CAMR (Centre for Applied Microbiology & Research in UK, actually Public Health England PHE; Report 670/00 dated 15th of December 2000).

Original documents are stored at the Particle Measuring System QA department, USA.

The current design features of a BioCapt Microbial Impactor is unchanged from the original time the certificate was issued by CAMR and therefore the efficiencies are not changed. In particular the document states as follows:

- a) the biological efficiency with *Staphilococcus epidermidis* at both 25 and 50 PM, is extremely effective;
- b) the physical efficiency has been shown to have the following d_{50} :
 - less than 1 μm (micron) at 50 LPM of air flow
 - less than 2 μm (micron) at 25 LPM of air flow

Date: September, 16, 2015

Signature



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Particle Measuring Systems
Corporate headquarters

PROCESS QUALITY SYSTEM

Site of Manufacture: Boulder CO, USA on behalf of Particle Measuring System
The Quality Management System is certified ISO 9001:2008 and ISO 13485:2003

