VALIDATION REPORT

SurgiCube® ID-nr	
SurgiCube® model	
Installation date	
Validation date	

PLEASE NOTE:

Make sure that the SurgiCube® is switched on for at least 30 minutes. The correct size sterile SurgiCube® drape must be applied according to the instructions.

Photo of the SurgiCube® in situ

Distributor name	
Address 1	
Address 2	
Postcode, City	
Country	
Phone	
Email	
Responsible contact	
Signature	

Customer name	
Address 1	
Address 2	
Department	
Floor, room number	
Postcode, City	
Country	
Phone	

Validation company	
Address 1	
Address 2	
Postcode, City	
Country	
Phone	
Email	

Type of validation	☐ New Installation ☐ Annual Validation ☐ Other, please specify: ☐ New HEPA filter validation ☐ Post-Event Validation

The following passed test results are required for release of the SurgiCube®:

Test	Criterium	Result
Filter Integrity Test	≤0,01% leakage	☐ Pass ☐ Fail
Air Velocity Test	0,45m/s ±10% deviation	☐ Pass ☐ Fail
Particle Concentration in the clean area	ISO 5 ≤3520 particles of 0,5µm/m.	☐ Pass ☐ Fail

Height: 75cm at instrument table
Depth: 80cm perpendicular to HEPA filter

Height: ±75cm at instrument table
Depth: 80cm perpendicular to HEPA filter

Copy of original measurement report(s) attached?	☐ Yes ☐ No
Copy of calibration reports equipment used attached?	☐ Yes ☐ No
Copy of HEPA H14 test certificate attached?	☐ Yes ☐ No

Remarks / Notes	

Additional test depending local regulations and requirements:

Colony Forming Units in the clean area	≤10 CFU's per m.	☐ Pass ☐ Fail
Colony Forming Units in the periphery	Reference points outside the clean area for comparison	☐ Yes ☐ No

Lab results attached	☐ Yes ☐ No
Photos of agar plates / strips attached	☐ Yes ☐ No
Calibration reports equipment used attached	☐ Yes ☐ No

Remarks / Notes	

Additional tests depending local regulations and requirements:

Test / info		Remarks / notes
Pressure hierarchy / Air Changes	☐ Yes ☐ No	
Particle Concentration in the periphery	☐ Yes ☐ No	
Protection Degree of the clean area	☐ Yes ☐ No	
Recovery time of the clean area	☐ Yes ☐ No	
Temperature	☐ Yes ☐ No	
Relative humidity	☐ Yes ☐ No	
Sound level (dBA)	☐ Yes ☐ No	

Remarks / Notes	

You can send this report to:

SurgiCube International BV
Seggelant-Noord 4
3237 MG Vierpolders
The Netherlands
E-mail: support@surgicube.com

If you have any additional questions, or in case you need more specific information, please contact us by e-mail (support@surgicube.com) or by phone (+31 181 760 600).

Responsible person: R. Hilberink	Sign:	Date: