V1.3.1

3DP Nasopharyngeal swab technical report template

Disclaimer:

I. This technical report template is written by National Additive Manufacturing Innovation Cluster (NAMIC) and its task force members, consisting of manufacturers, NUS, NUHS and TÜV SÜD as independent third party, to provide technical considerations for 3D printed nasopharyngeal swabs for emergency covid-19 pandemic usage in Singapore.

II. Users of this template must comply to 3D Printing guidance provided by Health Science Authority (HSA) of Singapore website https://www.hsa.gov.sg/announcements/regulatory-updates/guidance-on-3-d-printing-of-essential-medical-devices-and-accessories-for-use-in-covid-19-(coronavirus-disease-2019)-situation

III. None of the tests and assessments performed constitute a certification of medical devices.

IV. All scope of work is subjected to the approval of Health Science Authority (HSA) of Singapore. The task force, including TÜV SÜD as an independent test laboratory does not act on behalf of HSA.

COMPANY NAME			
Company name			
Contact Person			
DETAILS			
Product Name			
Design version			
Additive Manufacturing Technology used			
Material used			
Manufacturing Site			
Manufacturing Site Location			
DESIGN VALIDATION			
Value	Req ID	Description	Fulfilled?
Material review	D01	Materials to be used is CE Mark or FDA certified to be biocompatible as per relevant clauses of ISO10993 and sterilizable.	☐
Mechanical Properties	D02	Finished product has been tested for - tensile properties as per ISO 527 - flexural properties per ISO 178 - torsional properties using appropriate methods. Pass/Fail is measured against manufacturer's claims.	☐
	D03	Porous features, such as the swab head, need to be critically assessed for brittleness	☐
Bioburden, Sterility	D04	Finished product has been tested for - Bioburden Validation and Estimation as per ISO 11737-1 - Sterility Validation (Bacteriostasis and Fungistasis) as per ISO 11737-2 - Sterility Test (without Bacteriostasis and Fungistasis) as per ISO 11737-2 - Autoclave, EO or ECH residual (if applicable) as per ISO 10993-7	☐

In-vitro tests, efficacy	D05	The prototypes have undergone *in vitro* testing in the Molecular Diagnostic Laboratory comparing their ability to absorb SARS CoV-2 RNA, to release SARS CoV-2 RNA from the swab when appropriate (in order to measure SARS CoV-2 RNA) and to not inhibit the method of detecting SARS CoV-2 RNA (by PCR) with the current commercial swab in use.	☐
Clinical trial or clinical experience	D06	Clinical experience with the prototype will be achieved by obtaining feedback from clinicians experienced in nasopharyngeal swab use with regard to ease of use of the prototype swab compared to the standard commercial swab, and from swabbed patients regarding their comparative experience with the prototype swab and the standard commercial swab. Additionally, positive and negative results from SARS CoV-2 RNA detection by the prototype and the standard commercial swab will be compared.	☐
Instructions to users	D07	Specific instructions for safe and effective use of the 3-DP medical device should be provided including essential warnings, precautions and contraindications if any.	☐
		All of the above are fulfilled	☐
PRODUCTION QUALITY ASSURANCE			
Value	Req ID	Description	Fulfilled?
Quality Management System	P01	All manufacturing activities including additive manufacturing and post-manufacturing processes (such as UV curing) should be performed within a ISO13485 compliant quality management system.	☐
	P02	A process flow chart (including the post printing processing steps) is available.	☐
Risk Assessment	P03	A risk assessment is conducted to cover all quality risks is established	☐
Sampling Plan	P04	A quality control sampling plan with batch testing frequency and sample size, using established sampling methods such as ISO2859 is established. Inspection and pass/fail criteria should be specified, such as warpage degree, visible crack size, spots etc	☐
Trained /skilled personnel	P05	Training records of AM machine operator by machine provider is established	☐
Work instructions and checklist	P06	All required steps for the production and all related work instructions are established. AM machine operator has a checklist to follow.	☐
Qualified systems and processes	P07	Qualification of the selected systems/processes to produce consistent parts is conducted. Installation and Operational Qualification (IQ and OQ) of Systems and processes are in place.	☐
Production environment and mediums	P08	Atmosphere conditions such as temperature, humidity, room air flow is suitable and recorded	☐
Data preparation (parameter settings)	P09	Part placement orientation and support are suitable and evaluated	☐
	P10	Slice data generation. Definition of layer height provided; Defined parameter set are recorded.	☐
	P11	Build data (3D-file, parameters, etc.) for basic traceability are archived and stored in secured, safe location for retrieval	☐
Feedstock management	P12	Material selection, storage environment and change control are in place	☐
System preparation	P13	Preparatory steps (indicated by the manufacturer) for the restoration of the initial machine state for the start of the following production run with checklist or Work	☐

		instruction, e.g. inspection of system, cleaning of chamber, refilling of feedstock are established	
Setup for production run	P14	Feedstock state in the machine such as State (Humidity, Damage, Temperature etc.) are recorded	☐
	P15	Sufficient feedstock and support material are available	☐
System operation	P16	Checklist/tutorial is provided by machine provider for the indicated operating steps by the machine operator	☐
	P17	Logging/documenting the production with as much data as possible (e.g. process parameters, number of layers)	☐
System related post processing	P18	Part removal work instruction is available and followed	☐
	P19	System to clean-up AM machine work instruction is available and followed	☐
Part specific post-processing	P20	System to clean-up part to remove all residual materials such as powder/resin or process residues	☐
	P21	System to ensure production facility supports sterility production is established	☐
Traceability	P22	Labelling should include sufficient information to identify or to trace the device including but not limited to the manufacturing lot/batch information	☐
All of the above are fulfilled			☐

DEVIATIONS FROM REQUIREMENTS (if any)

ADDITIONAL INFORMATION (if any)