A GLASS BIOREACTOR SYSTEM FOR CULTURING ANIMAL CELLS UNDER CONTROLLED CONDITIONS WITH CONTROLLERS AND SOFTWARE-ENABLED PRECISE CONTROL AND MONITORING OF BIOPROCESSES AND SCALING THEREOF

1. OPERATIONAL REQUIREMENTS

1.1. PART A - EQUIPMENT

ID	Requirements	Priority/[Must - M, Option - O]	Classification/ [GxP- G, Technical - T, Other - O]	URS-compliant/[Yes No]	Notes
1.1.	**Process/Measurement Requirements/**				
1.1.1.	The system is designed to allow the cultivation of animal cells on a laboratory scale in working volumes of 1L, 3L, 7L	**M**	G		
1.1.2.	Simultaneous oxygenation control in glass tanks with working volumes V= 1L, 3L, 7L	**M**	G		
1.1.3.	Simultaneous temperature control in glass tanks with working volumes V= 1L, 3L, 7L	**M**	G		
1.1.4.	Regulation of exhaust gas in glass tanks with working volumes V= 1L, 3L, 7L	**M**	G		
1.1.5.	Sterilisation possibility of bioreactors with working volumes V= 1L, 3L, 7L in a steam autoclave at 121^{o}C for 20 minutes	**M**	G		
1.1.6.	Possible simultaneous pH reading with a reusable probe in glass tanks with working volumes V= 1L, 3L, 7L	**M**	G		
1.1.7.	Possibility to add scales to the system to weigh the bioreactor and enable precise control of the addition and removal of media from the bioreactor	**O**	G		
1.1.8.	Recirculation of the medium during the process with the possibility of dialysis and discharge to wastewater	**M**	G		
1.1.9.	The system is to allow receiving and adding the culture medium.	**M**	G		
1.1.10.	The system is to allow receiving cultures with cells	**M**	G		
1.1.11.	The following sensors are required: temperature sensor, pH, DO, CO2	**M**	G		
1.1.12.	Possibility of precise dosing of culture medium	**M**	G		
1.1.13.	Ability to remove forming foam	**M**	G		
1.1.14.	System efficiency ensures that the process is carried out in bioreactors with working volumes V= 1L, 3L, 7L	**M**	G		
1.1.15.	Transparent borosilicate glass vessels for animal cell culture	**M**	**G**		

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1.1.16.	Bioreactors with a heating jacket and a cooling loop	**M**	**G**		
1.1.17.	Cooling medium - water	**M**	**G**		
1.1.18.	Removable top cover with fastening and positioning screws	**M**	**G**		
1.1.19.	It has a system facilitating the removal of the top cover	**M**	**O**		
1.1.20.	All sensors and necessary openings located in the top covers of the bioreactors	**M**	**G**		
1.1.21.	Each of the bioreactor glass tanks has its own base for their stable mounting	**M**	**G**		
1.1.22.	Customisable configuration of the sensors and openings in the top cover of each bioreactor adjusted to the user's needs	**M**	**G**		
1.1.23.	Top-mounted agitator motor with smooth speed regulation	**M**	**G**		
1.1.24.	Agitator type: 1 for each bioreactor as proposed by the supplier, suitable for the culturing of animal cells in suspension and on microcarriers	**M**	**G**		
1.1.25.	Working volume of up to 1L, 3L, 7L	**M**	**G**		
1.2.	**Material/Construction Requirements**				
1.2.1.	All materials in contact with the pure medium or the product are made of 316L steel or other material certified for food use	**M**	**G**		
1.2.2.	All materials in contact with the medium and the product are resistant to acid and alkaline washing	**M**	**T**		
1.2.3.	The load-bearing frame, external cladding and structural components are made of corrosion-resistant materials	**M**	**T**		
1.3.	**Safety/Ergonomics/Handling requirements**				
1.3.1.	The system has a separate engineering computer	**M**	**O**		
1.3.2.	The system has a separate computer for data archiving of at least RAID 1O class	**M**	**O**		

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1.3.3.	The system is equipped with an operating station	**M**	**O**		
1.3.4.	The system is based on dedicated open-architecture software	**M**	**O**		
1.3.5.	The software allows the implementation of additional scripts	**M**	**O**		
1.3.6.	The software enables the transfer of data obtained at laboratory scale to an industrial scale	**M**	**O**		
1.3.7.	The system allows simultaneous control of processes carried out in at least 3 bioreactor tanks	**M**	**O**		
1.3.8.	The software allows adding additional elements, i.e. sensors and components from other manufacturers	**M**	**O**		
1.3.9.	In all sensors, sending and receiving signals is carried out by a relay tower without any logic control or processor	**M**	**O**		
1.3.10.	The entire process is controlled and precisely monitored by an industrial-grade logic controller	**M**	**O**		

1.2. PART B - COMPUTERISED SYSTEMS

ID	Requirements/	Priority/[Must - M, Option - O]	Classification/ [GxP- G, Technical - T, Other - O] Safety - S]	URS-compliant [Yes/No].	Provider notes/ .
1.	**Staff training**				
	The supplier will provide initial training on the use of the system with documentation confirming its completion	M	G		
2.	**Automation system requirements**				
	Fully automatic process	M	G		
	Process visualisation with adjustable settings	M	G		
	Formulation system	M	G		
	Comprehensive process monitoring	M	G		
	Recording and archiving of process data	M	G		
	Possibility of process analysis	M	G		
	Control panel required	M	G		

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ID	Requirements/	Priority/[Must - M, Option - O]	Classification/ [GxP- G, Technical - T, Other - O] Safety - S]	URS-compliant [Yes/No].	Provider notes/ .
	Integrated access levels	M	G		

2. DOCUMENTATION

2.1. GENERAL REQUIREMENTS

ID	Requirements/	Priority/[Must - M, Option - O]	Classification/[GxP-G, Technical - T, Other - O].	URS-compliant [Y/N]	Notes/
2.1	**Traceability**				
	Each document must have a unique number or be marked in a different way to ensure identification (date of preparation, title and version, etc.) with a copy marker if applicable	M	G		
	Each document must have the date of preparation/issue	M	G		
	Drawings/views must reference Author, Version, Date prepared, Format and Scale (if applicable)	M	G		

DOCUMENTATION LIST

ID	Requirements	Priority [Must - M, Option - O]	Classification/ [GxP- G, Technical - T, Other - O] Safety - S]	Language/	Electronic Version [Yes/No]	URS-compliant/ [Y/N]	Notes/
2.2	**Documentation List**						
	Description of destination	M	G	Polish/English			
	A functional description including at least a description of the equipment and the characteristics of the device	M	G	Polish/English			
	Description of the design of all device components	M	G	Polish/English			
	Transport guidelines	M	T	Polish/English			
	Installation and use guidelines	M	T	Polish/English			
	Commissioning description	M	G	Polish/English			
	Service description	M	G	Polish/English			
	Washing guidelines	M	G	Polish/English			

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	OHS requirements	M	S	Polish/English			
	Control and maintenance description	M	G	Polish/English			
	Description of emergency procedures	M	G	Polish/English			
	List of critical and "fast wearing" spare parts	M	T	Polish/English			
	List of commercial and spare parts	M	G	Polish/English			
	Data sheets/instructions for installed components	M	G	Polish/English			

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3. SYSTEM DELIVERY, INSTALLATION, QUALIFICATION AND VALIDATION REQUIREMENTS

ID	Requirements/	Priority/[Must - M, Option - O]	Classification/ [GxP- G, Technical - T, Other - O]	URS-compliant [Y/N]	Notes/
	Delivery, Installation, Validation				
	The supplier shall submit a written proposal for a quotation within 1 week of receipt of this document.	M	O		
	The supplier will provide training in the operation of the systems, along with training documentation. The supplier will issue a training certificate.	M	G		
	The supplier shall install the system in accordance with the terms of this URS.	M	G		

4. SERVICE, CALIBRATION, SYSTEM MAINTENANCE REQUIREMENTS

ID	Requirements	Priority [Must - M, Option - O]	Classification/ [GxP- G, Technical - T, Other - O] Safety - S]	URS-compliant [Y/N]	Notes/
	Service, Calibration, Maintenance				
	The supplier will provide support for the supply of spare parts for 3 years from the date of system installation.	**O**	**T**		
	The supplier will provide service and technical support for 3 years from the date of system installation.	**M**	**T**		
	The supplier will provide system calibration services for 2 years from the date of system installation.	**M**	**T**		
	The supplier will provide a 2-year warranty period from the date of installation.	**M**	**T**		