



Issue: 81/2022/M/RNA

Appendix no 1

In connection with the implementation of the project No. 2021 / ABM / 05/00005 under the name "**Development of Innovative Therapeutic Solutions using RNA technology (TransformRNA - mRNA Therapeutics generation platform)**" co-financed by the Medical Research Agency, Celon Pharma S.A. invites you to submit offers:

The subject-matter of the procedure: *Microfluidic mixer intended for lipid nanoparticles production in GMP with R&D fluid path – amount: 1*

The device in question must be brand new, manufactured not earlier than in 2022, not used in any laboratory, not exhibited at conferences or trade fairs. The device must meet the technical and functional requirements specified in the description of the subject-matter of the contract, including delivery and installation. Description of the subject-matter of the contract presents the minimal requirements of the device being the subject-matter of the contract. The Contractors entering the procurement should offer a device with parameters equal to or greater than those indicated below.

Description of the subject-matter

	General requirements for the microfluidic mixer intended for lipid nanoparticles production in GMP	Parameters of subject-matter (to be filled by the supplier)
1.	Be able to work as continuous flow system	
2.	Be able to produce lipid nanoparticles in time-invariant manner	
3.	Be compliant with GMP requirements	
4.	Be able to mix two solutions, one of them consists of ethanol	
5.	Be able to mix these solutions in a nonturbulent manner	
6.	Be able to in line dilute produced nanoparticles with a third solution	
7.	Should be controlled by a computer	
8.	Be able to work with single-use fluid paths	
9.	Should come with all parts and tools enabling working on it	
10.	Must work with electricity: 230V and 50-60 Hz	
11.	Should contain calibration tools	
12.	Should contain all GMP documentation, including product contact materials documentation	

Celon Pharma S.A.

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Organ rejestrujący: Sąd Rejonowy dla Miasta Stołecznego Warszawy w Warszawie
XIV Wydział Gospodarczy Krajowego Rejestru Sądowego
Prezes Zarządu: Maciej Wieczorek
KRS: 0000437778
Kapitał zakładowy: 5 100 000 PLN
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	Minimal requirements for the microfluidic mixer	Parameters of subject-matter (to be filled by the supplier)
1.	Minimum production volume NOT MORE than 1 L (pre-dilution)	
2.	Maximum production volume not less than 50 L (pre-dilution)	
3.	Minimum formulation flow rate NOT MORE than 60 mL/min	
4.	Maximum formulation flow rate not less than 200 mL/min	
5.	Minimum hold-up volume NOT MORE than 100 mL	
6.	Minimum waste volume (pre-dilution) NOT MORE than 150 mL	
7.	Minimum dilution flow rate NOT MORE than 60 mL/min	
8.	Maximum dilution flow rate not less than 1000 mL/min	
9.	Minimum flow rate ratio between two main solutions NOT MORE than 1:1	
10.	Maximum flow rate ratio between two main solutions not less than 5:1	
11.	Minimum flow rate accuracy for two main solutions NOT MORE than +/- 2%	
12.	Minimum flow rate accuracy for dilution solution NOT MORE than +/- 5%	
13.	Minimum accuracy of pressure readout (two main solutions) NOT MORE than +/- 10%	

	Minimal requirements for the R&D fluid path	Parameters of subject-matter (to be filled by the supplier)
1.	Should be compatible with 0.5N NaOH	
2.	Should not be single use	
3.	Should be able to work with pressure not less than 500 psi	
4.	Should contain appropriate mixer (cartridge) for required fluid flows	
5.	Should contain all needed tubing and connections	

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Additional requirements		
Warranty	Minimum warranty period: 12 months	
Post-warranty service	The supplier will provide access to spare parts and post-warranty service for at least 5 years following the date of contract performance	
User manual	Printed user manual in Polish or in English with a translation into Polish	
Training	The supplier will conduct training covering the principles of use and basic service activities for the Contracting Party's personnel (unlimited number of participants)	

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(Signature by Tender's authorized person)

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