Liofilchem®

EU DECLARATION OF CONFORMITY FOR IN VITRO DIAGNOSTIC MEDICAL DEVICES

Manufacturer Name	Liofilchem® S.r.l.
Manufacturer Address	Via Scozia, 64026 Roseto degli Abruzzi (TE) - Italy
SRN (Single Registration Number)	IT-MF-000026495
Basic UDI-DI, Name of the Device(s), Product code(s), Intended Purpose	See Table no.1
Classification in accordance with the rules set out in Annex VIII	Class C
References to CS used and in relation to which conformity is declared	Not yet applicable
Description of the conformity assessment procedure performed:	Annex IX
Identification of the certificate issued:	EU Quality Management System Certificate (IVDR) No. V12 071067 0008
Notified Body Name:	TÜV SÜD Product Service GmbH
Notified Body Identification Number:	0123

This declaration of conformity is written according to Annex IV of Regulation (EU) 2017/746 and is issued under the sole responsibility of Liofilchem S.r.l.
We hereby declare that the in vitro diagnostic medical device specified above meet the provision of the Regulation (EU) 2017/746 for in vitro diagnostic medical devices.
All supporting documentation is retained at the premises of the manufacturer.

Roseto degli Abruzzi (TE),
07.03.2025

Signature:



Technical Director
(Dr. Silvio Brocco)

Liofilchem®

Table no.1

Code	Description	Basic UDI-DI	Intended purpose
Antibiotic Discs			
9253 9253/1 9253/2	Imipenem-relebactam (10+25) I/R 35 µg	805518287ATBDISC253Z3	Imipenem-relebactam (10+25) I/R 35 µg is an *in vitro* semi-quantitative method for antimicrobial susceptibility of clinical isolates tested on agar media using overnight incubation. The test is used against the following microorganisms: • Gram-negative bacteria • Enterobacterales • *Pseudomonas aeruginosa*
9270 9270/1 9270/2	Cefepime-enmetazobactam (30+20) FPE 50 µg	805518287ATBDISC270Z3	Cefepime-enmetazobactam (30+20) FPE 50 µg is an *in vitro* semi-quantitative method for antimicrobial susceptibility of clinical isolates tested on agar media using overnight incubation. The test is used against the following microorganisms: • Gram-negative bacteria • Enterobacterales
9272 9272/1 9272/2	Aztreonam-avibactam (30+20) AZA 50 µg	805518287ATBDISC272Z7	Aztreonam-avibactam (30+20) AZA 50 µg is an in vitro semi-quantitative method for antimicrobial susceptibility of clinical isolates tested on agar media using overnight incubation. The test is used against the following microorganisms: • Gram-negative bacteria • Enterobacterales