

ESPI REPORT NO. 9/2026 | 18 March 2026 | Submission of documentation in the IVDR certification process for the BACTEROMIC system with the UNI FAST Panel

The Management Board of Scope Fluidics S.A. (“**Scope**”) hereby informs that Bacteromic sp. z o.o. (“**Bacteromic**”), a subsidiary of Scope developing the BACTEROMIC project, has submitted to a notified body the documentation required to initiate the conformity assessment process under IVDR (the “**IVDR Certificate**”) for the BACTEROMIC system with the UNI FAST Panel. The remaining documentation will be submitted by Bacteromic on a rolling basis.

Bacteromic has submitted for certification the UNI FAST Panel, which includes 24 antibiotics and 48 corresponding drug–bug combinations, enabling antimicrobial susceptibility testing within 6–8 hours. In the opinion of the Management Board, the composition of the UNI FAST Panel supports the planned commercial activities for the BACTEROMIC system. At the same time, as previously communicated by Scope, efforts are ongoing to further expand the portfolio of drug–bug combinations within the UNI FAST Panel, both with a view to FDA certification and IVDR certification for an extended version of the panel.

The IVDR Certificate for the BACTEROMIC system with the UNI FAST Panel is expected to be obtained in mid-year. It should be noted that the notified body may raise questions to Bacteromic regarding the presented data or request that Bacteromic conduct additional studies. This may extend the certification process and result in a delay in obtaining the IVDR Certificate; however, at this stage, the Management Board of Scope does not identify any material risks in this regard. At the same time, the Company informs that the final number of antibiotics and drug–bug combinations will depend on the assessment of the notified body and may be lower than the number indicated in the documentation submitted for evaluation.