

ESPI REPORT NO. 7/2026 | 20 February 2026 | CE-IVDR certification of the BACTEROMIC system

Further to Current Report No. 26/2025, the Management Board of Scope Fluidics S.A. (**'Scope'**) reports that a CE-IVDR certificate confirming compliance with the requirements of the In Vitro Diagnostics Regulation (the **'IVDR Certificate'**) was obtained for the BACTEROMIC system with the UNI Panel and the current interpreter. The BACTEROMIC system is being developed by Bacteromic sp. z o.o. (**"Bacteromic"**), a wholly-owned subsidiary of Scope.

At the same time, compliance with IVDR requirements was confirmed for the devices forming part of the BACTEROMIC system, i.e. the analyser and the filling device. Accordingly, the complete system – the analyser, the filling device, the interpreter, and the UNI Panel – is CE marked following the conformity assessment and may be placed on the market in the European Union and in countries recognising IVDR requirements.

The IVDR Certificate was granted for the UNI Panel version comprising all 30 specified antibiotics and the corresponding 56 antibiotic–bacterium combinations (drug-bug combinations), with ESBL resistance-mechanism detection and software enabling antibiotic susceptibility assessment in 16 hours.