

**To the attention of economic operators requesting approval of the activity of  
installation and/or maintenance of medical gas distribution systems**

Following the appearance of Order no. 2412 of 15.09.2022 on approval of the technical regulation "Regulation for hospital constructions - NP 015-2022" issued by the Ministry for Development, Public Works and Administration and the numerous requests for clarifications regarding the provisions of this Order, please be advised that:

- An economic operator (EO) may request approval of the activity of installing medical gas distribution systems (SDGM) if it has signed a contract (for renewal)/has documented the fact that in order to carry out this activity, it shall sign a contract with a manufacturer of SDGM who undertakes the developed project in compliance with the provisions of SR EN ISO 7396, revised edition in force and the CE marking of the final product and on whose behalf the economic operator carries out / shall carry out the installation activity.

Any commissioning of a new SDGM, but also any modification / expansion of an existing SDGM (a new SDGM or a part of the hospital infrastructure) is considered an "installation". The SDGM manufacturer is exempt from the approval.

- An economic operator (EO) may request the approval of the maintenance of some SDGM already installed in healthcare units, provided that the requirements of being equipped with equipment suitable for carrying out the activity requested for approval and of sufficient and qualified/trained personnel for the activity performed/ the field in which they work are met. The EO approved for maintenance activities for the SDGM must perform an assessment of the SDGM to see if the requirements of the SR EN ISO 7396 standard are met. If the standard's requirements are met, the economic operator may, if necessary, replace component parts (pipes, valves, ramps, consoles, oxygen concentrators, etc.) with corresponding ones bearing the CE marking (for medical use). If the SDGM does not meet the requirements of the standard, it is necessary to contact a certified SDGM manufacturer in order to develop a project

to modify an already existing system so that the SDGM is brought into compliance with the standard.