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BACKGROUND



The project stems from the need to support the maintenance of the European Medical Device Nomenclature (EMDN), established by article 26 of Regulations (EU) 2017/745 and article 23 of Regulations (EU) 2017/746 and made available free of charge by the European Commission in order to facilitate the operation of the European medical device database, "EUDAMED".



OBJECTIVES AND EXPECTED RESULTS

The project aims to achieve a high quality, clear and accurate EMDN that is regularly maintained through the following support activities to the European Commission:

- periodic update of the EMDN
- communicate information and provide clarifications on the nomenclature to Member States' authorities and stakeholders
- make available tools to support the use of the EMDN
- collaborate with World Health Organization



Co-funded by the European Union Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or European Health and Digital Executive Agency (HaDEA). Neither the European Union nor the granting authority can be held responsible for them.

SMEMDN PROJECT

SUPPORTING THE MAINTENANCE OF THE EUROPEAN MEDICAL DEVICE NOMENCLATURE



Supporting the Maintenance of the European Medical Device Nomenclature

TO WHOM IT IS ADDRESSED

Project activities are intended for economic operators that use EMDN nomenclature, Member States' authorities and stakeholders involved in the medical device sector which may:

- submit proposals to update the EMDN nomenclature and the information documents
- contact the helpdesk to receive clarification on the structure and the rationale of the EMDN
- attend EMDN training workshops
- use shared information documents

SMEMDN Supporting the Maintenance of the European Medical Device Nomenclature

PROJECT STRUCTURE

The project is structured in 5 work packages:

- WP1 Project Management & Coordination
- **WP2** Communication & Dissemination
- WP3 Evaluation
- WP4 Sustainability
- **WP5** EMDN management

PARTNERS

The consortium is composed:

- the Italian Ministry of Health, as beneficiary
- the Autonomous Region of Friuli Venezia Giulia, as affiliated entity

DURATION OF THE PROJECT

The SMEMDN project started on 20 March 2023 and will last 36 months

FOR FURTHER INFORMATION

Website of Minister of Health Website of Friuli Venezia Giulia autonomous Region

