

Aktuálny vývoj plného nasadenia EUDAMED

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Sekcia zdravotníckych pomôcok
Štátny ústav pre kontrolu liečiv

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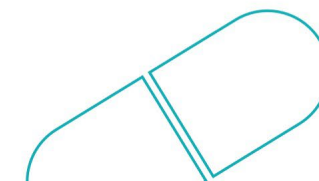
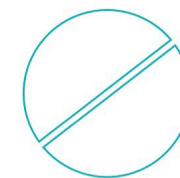
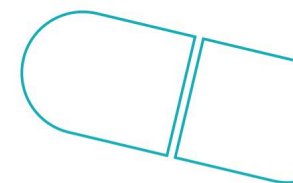
SARAP, 6. jún 2023



EUDAMED - Európska databáza zdravotníckych pomôcok

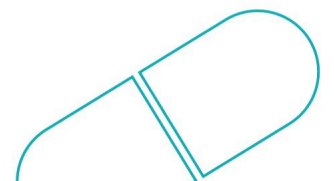
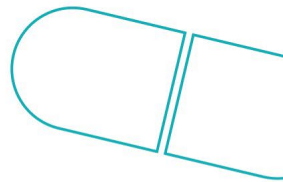
- Vytvorenie európskej databázy zdravotníckych pomôcok (EUDAMED) je jedným z kľúčových aspektov v rámci nových pravidiel týkajúcich sa zdravotníckych pomôcok (Nariadenie (EÚ) 2017/745) a diagnostických zdravotníckych pomôcok in vitro (Nariadenie (EÚ) 2017/746).
- EUDAMED poskytne živý obraz o životnom cykle zdravotníckych pomôcok, ktoré sa sprístupňujú v Európskej únii (EÚ). Bude integrovať rôzne elektronické systémy na zhromažďovanie a spracovanie informácií o zdravotníckych pomôckach a prepojených spoločnostiach (napr. výrobcach). Cieľom databázy EUDAMED je zvýšiť celkovú transparentnosť, a to aj prostredníctvom zlepšenia prístupu k informáciám pre verejnosť a zdravotníckych pracovníkov, a posilniť koordináciu medzi rôznymi členskými štátmi v EÚ.

<https://ec.europa.eu/tools/eudamed/#/screen/home>



EUDAMED

1. modul registrácie hospodárskych subjektov
2. modul UDI / registrácie pomôcok
3. modul notifikovaných osôb a certifikátov
4. modul klinických skúšaní a štúdií výkonu
5. modul vigilancie a dohľadu výrobcu po uvedení na trh
6. modul trhového dohľadu

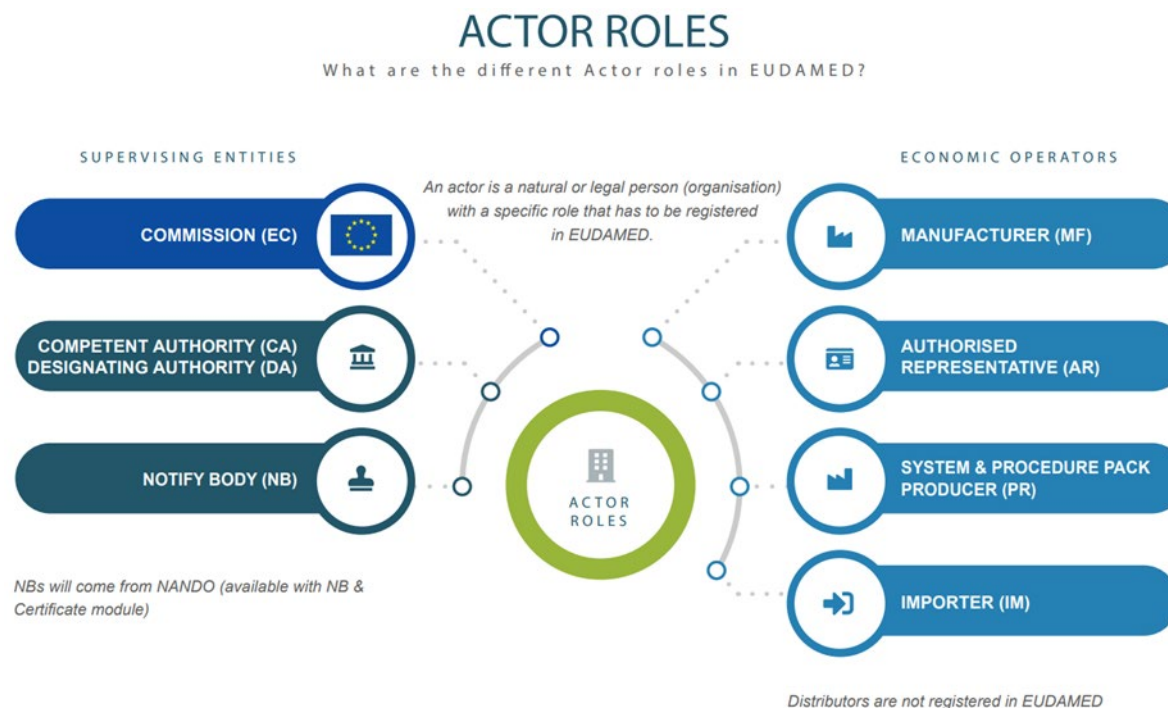


Modul registrácie hospodárskych subjektov

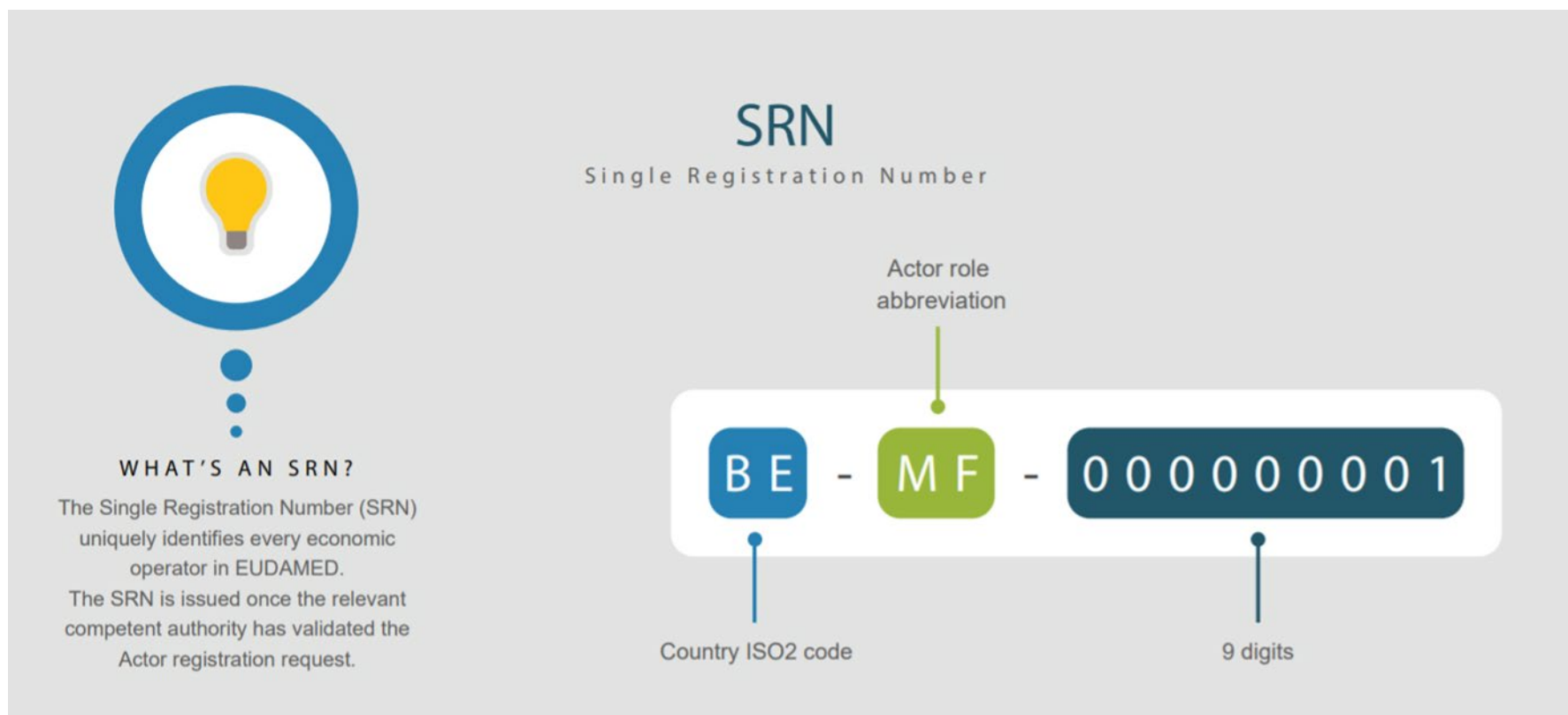
umožňuje hospodárskym subjektom predložiť prostredníctvom žiadosti o registráciu informácie potrebné na získanie jednotného registračného čísla

SRN = Single Registration Number

The screenshot shows the EUDAMED - European Database on Medical Devices interface. The page title is "EUDAMED - European Database on Medical Devices" and the current page is "Economic Operators". Below the title, there is a search bar with the text "Economic Operators" and a sub-header "The search for economic operators allows you to search and retrieve all records that contain the search terms you enter. At least one search criteria is mandatory." The search criteria section includes a "Search criteria" dropdown and a "Filters" section with input fields for "Name or abbreviated name", "SRN", "Role", "Country", and "Competent Authority". There is also a "Result options" section with a toggle for "Include historical version". At the bottom, there are "Search" and "Clear search" buttons.



Registrácia hospodárskych subjektov SRN



WHAT'S AN SRN?
The Single Registration Number (SRN) uniquely identifies every economic operator in EUDAMED. The SRN is issued once the relevant competent authority has validated the Actor registration request.

SRN
Single Registration Number

Actor role abbreviation

Country ISO2 code

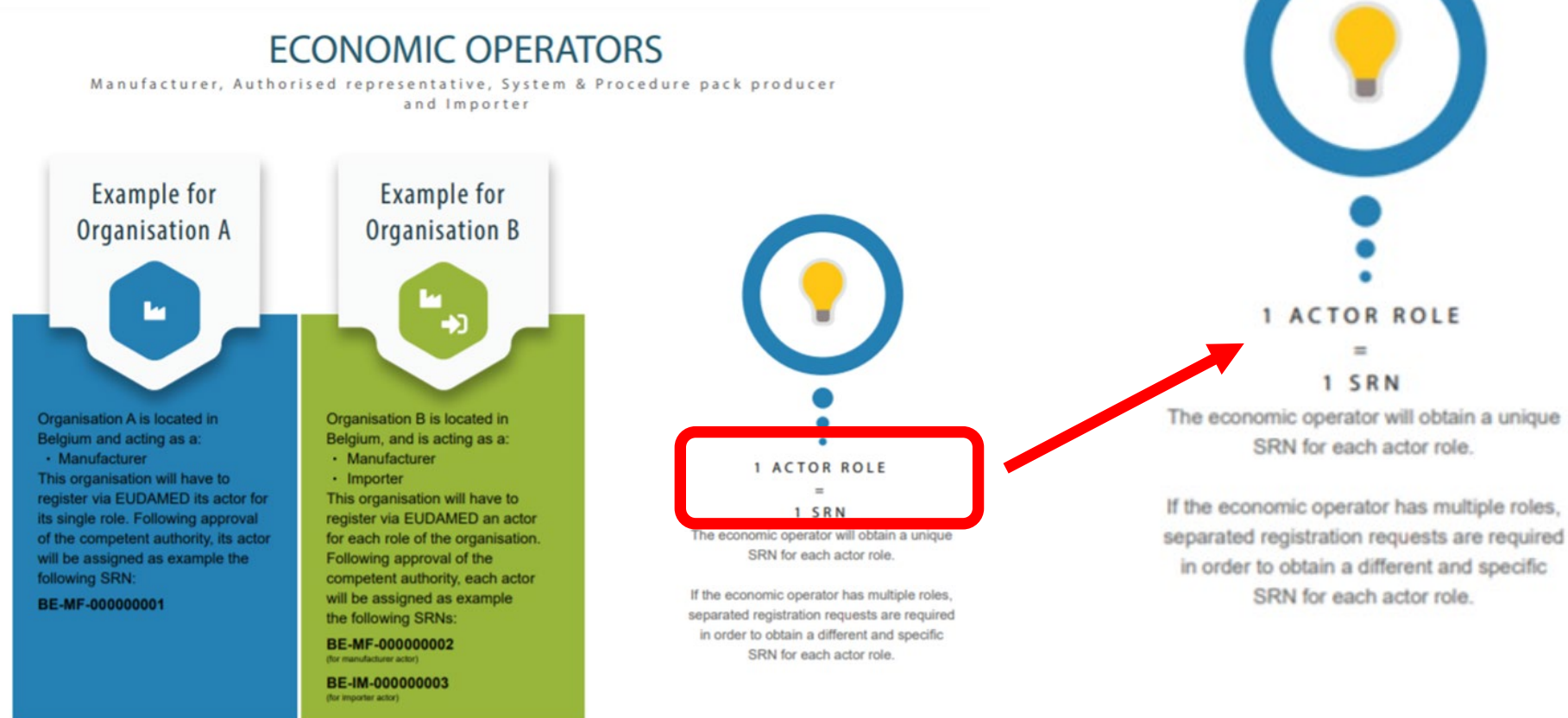
9 digits

BE - MF - 000000001

The infographic illustrates the structure of the SRN (Single Registration Number). It is composed of three parts: a two-letter Country ISO2 code (BE), a two-letter Actor role abbreviation (MF), and a 9-digit number (000000001). The components are separated by hyphens. A lightbulb icon is used to represent the concept of an idea or definition.

Hospodársky subjekt a SRN

Po posúdení a schválení žiadosti príslušným úradom (CA) vygeneruje Eudamed hospodárskemu subjektu SRN.



Modul UDI / registrácie pomôcok

REGISTRATION PROCESS FOR REGULATION DEVICES

What's the process to register a Regulation device in EUDAMED?



High risk class devices, covered by a Type Examination or Technical Documentation Certificate (for devices referred to in MDR Art 29(3) or in IVDR Art 26(2)) **requires the Notified Body confirmation of device data before the device can be publicly available.**



Modul notifikovaných osôb a certifikátov

CERTIFICATE PAPER VERSION UNIQUE IDENTIFIER

The paper Certificate version **is identified by a unique number** which is the "**NB number + Certificate number (+ possibly 'Revision number')**".



Current Actor in EUDAMED
(Notified Body Identification number from Nando is automatically identified from user acting on behalf of NB.)

EUDAMED CERTIFICATE DATA VERSION IDENTIFICATION

The EUDAMED Certificate data version **is identified by** the "**Certificate paper version unique identifier**" and the "**EUDAMED version number**".



+


EUDAMED
version number

The EUDAMED version number is incremented for any update of a certificate like for the certificate paper version identifier. However, in case of decision (Withdrawn, Suspended, Re-instated ...) applied on a certificate, it will mean a new EUDAMED version although not a new Certificate paper version.

EUDAMED – časová os

EUDAMED Time line

The European Commission planning – June 2022



| Q4 2023 | Q1-Q2 2024 | Q2 2024 | Q2 2024 | Q4 2024 | Q2 2026 |
|---|-------------------|--|--|---|--|
| End of the EUDAMED MVP ¹ development for all six modules | Independent Audit | Audit results presented to the Medical Devices Coordination Group (MDCG) | EUDAMED has achieved full functionality following the outcome of the Audit. Publication of a Commission notice in the <i>Official Journal of the European Union</i> (OJEU) | End of 6 months transitional period after publication of the notice in the OJEU. The full EUDAMED system (all 6 modules) is released. The use of EUDAMED becomes mandatory as regards obligations and requirements related to Actors, Vigilance, Clinical Investigation & Performance Studies and Market Surveillance modules | End of 24 months transitional period after publication of the notice in the OJEU The use of EUDAMED becomes mandatory as regards obligations and requirements related to UDI/Device and NB & Certificate modules |

¹ EUDAMED Minimum Viable Product (MVP) means that the system developed implements at least the minimum Medical Devices Regulations requirements and allows competent authorities and all stakeholders to comply with their legal obligations.

Ďakujem za pozornosť

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