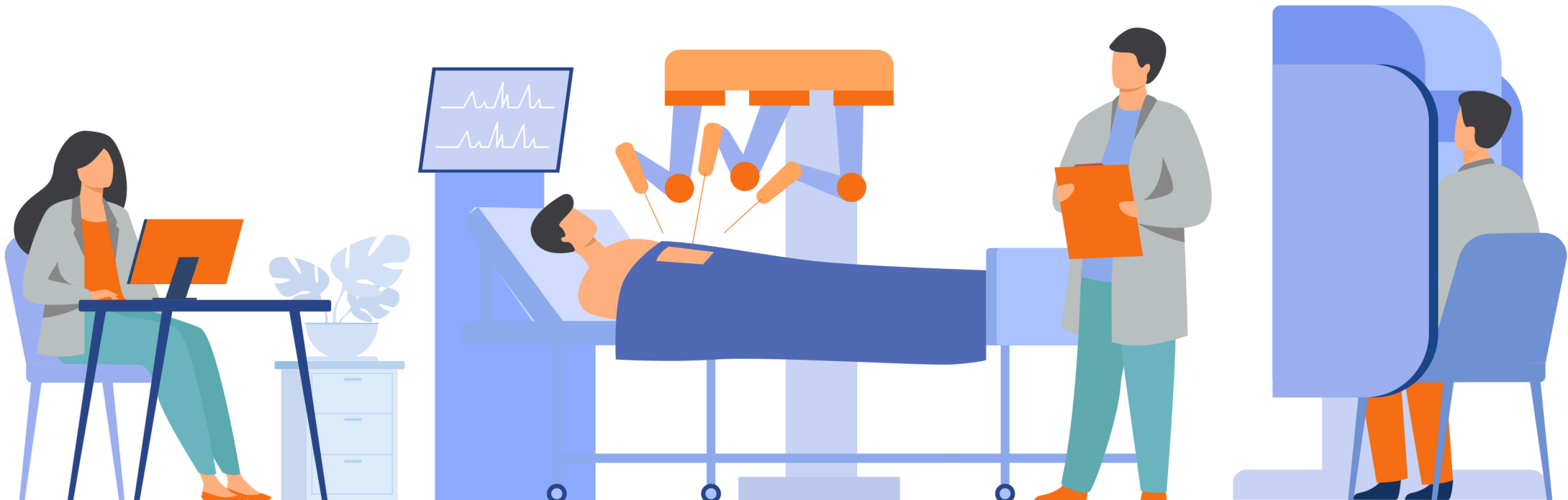


CASE STUDY

Translations for medical devices compliant with the EU MDR regulation



SCENARIO

→ THE CLIENT

Italian company specialized in the **development and production of patented solutions for infection control**, such as sterilizers, ultrasonic cleaners, water purification systems, sealing devices, and incubators.

→ THE REQUIREMENT

Translation of technical documentation into 22 EU languages in accordance with MDR EU regulations, including ongoing updates and ensuring terminological consistency.

→ TYPE OF DOCUMENTATION

User manuals for steam sterilizers intended for use by doctors and healthcare professionals.



TARGET LANGUAGES

Bulgarian
Czech
Croatian
Danish
Estonian
Finnish
French

Greek
English
Latvian
Lithuanian
Dutch
Polish
Portuguese

Romanian
Slovak
Slovenian
Spanish
German
Swedish
Hungarian



→ EU MDR 2017/745 REGULATION ON MEDICAL DEVICES

requires the translation of information related to the devices into the language of the Member State where the device will be marketed.

This involves:

- **Translating into all EU languages**
- **Expertise in technical and scientific translation**
- **Terminological consistency in the translation**



CHALLENGE

→ 22 DIFFERENT LANGUAGE COMBINATIONS

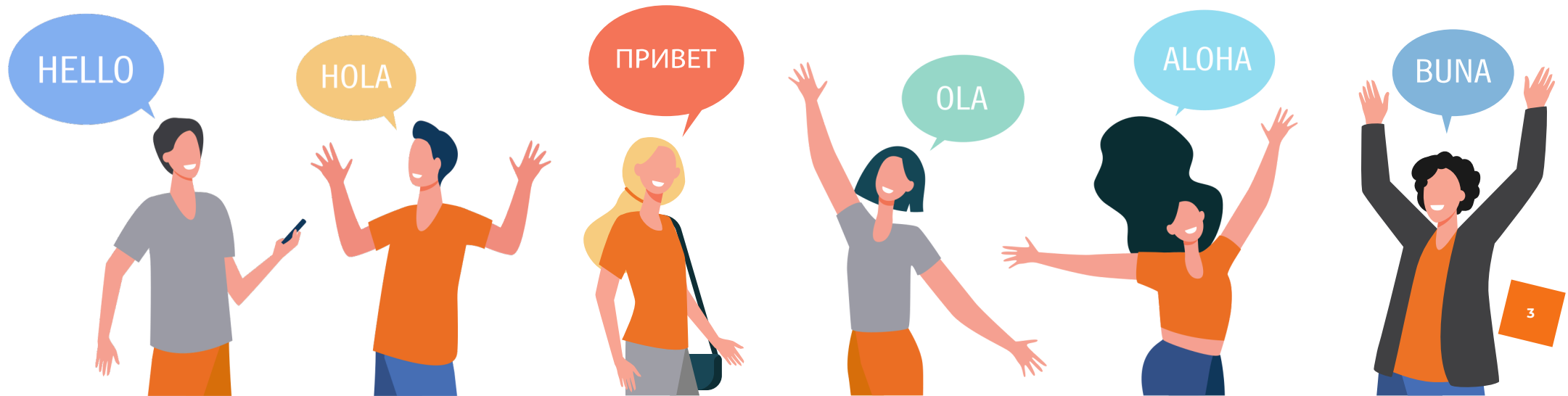
- Research and selection of **translators with appropriate specialization and expertise**
- **Coordination** of all resources involved in the project

→ CLIENT'S SPECIFIC REQUIREMENTS

- **Translation:** precise instructions to be shared with and followed by the translators
- **Formatting:** the translated manuals needed to match the length of the original Italian version
- **Addition of updates:** integrations to be translated as they are developed

→ CERTIFIED PARTNER

- Certifications for the translation services sector: **UNI EN ISO 17100:2015**
- Organization, management, and control model 231
- Aglatech14 for waste reduction



SOLUTION



DEDICATED INTERNAL TEAM FOR THE PROJECT

Project Manager, Vendor Manager, Editor, Linguists, Quality Specialist, and Technology Specialist, to ensure:

- **Work coordination**
- **Budget adherence** (renegotiation of rates to achieve the appropriate economic agreement)
- **Timeliness of deliveries**



POOL OF TRANSLATORS WITH EXPERTISE IN TECHNICAL LANGUAGE AND REGULATIONS

selected through **rigorous translation tests**



WORK TOOLS SHARED WITH TRANSLATORS AND CLIENTS

to gather **doubts and questions** regarding the translation and ensure **terminological consistency**



THE DOCUMENTS WE TRANSLATE

TRANSLATIONS FOR MEDICAL DEVICES

Instructions for use (IFU) and user manuals

Technical manuals for service and maintenance

User guides

Summary of safety and clinical performance

Declarations of conformity

Field safety notices





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