

With GAP analysis and Excel upload to EUDAMED registration

Primed Halberstadt Medizintechnik GmbH

Medical devices | Halberstadt am Harz | 450 Employees | 2.600 Products



**GAP ANALYSIS
OF DATA REQUIRED
BY EUDAMED**



**UPLOAD,
SIMPLE ADDING AND
VALIDATION OF DATA**



EUDAMED REGISTRATION



"With the UDI Manager, atrify already gives us the tool for single or bulk upload. With each data input I can be sure that atrify on the other side checks the values for completeness and plausibility before the data is forwarded to EUDAMED."

Phillip Kappe | Technology department | Primed Halberstadt Medizintechnik GmbH

Initial situation and challenge

The family owned and operated medical technology company Primed Halberstadt successfully sells its more than 2,600 devices worldwide. For their European market they faced a pressing challenge. To meet the EU MDR requirements they would need to register all of their European devices in the EUDAMED database. Due to the many nuances of the regulation it was difficult to get

a comprehensive overview of the product information required to compliantly register their specific devices. In addition, Primed Halberstadt needed to not only understand the EUDAMED specifications, but also find the most time and cost-efficient way to register and maintain their full product portfolio knowing they would continue to add further UDIs at later points in time.

REVEALING GAPS ✓

- Understanding EUDAMED specifications
- Check if required data is available in internal systems
- Capturing and merging data



*"Bringing the data together was not easy and should not be underestimated, but **atrify has been great in helping us do it**"*

UDI MANAGEMENT ✓

- Upload of 2.000 UDIs via Excel Bulk-Upload
- Possibility to easily add more items via Excel Upload or manually at any time
- Data Validation



"The UDI Manager supports here with the numerous validations of EUDAMED and already gives good feedback with the upload or entry of new product data."

EUDAMED REGISTRATION →

- Registration status can be viewed at any time in the UDI Manager
- Personal email notifications when registration status is updated



Next step:

Data transfer and successful EUDAMED registration