
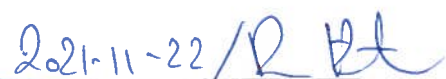


Declaration of GDPR Conformity	
Manufacturer:	Life Science Robotics ApS Sofiendalsvej 83 DK-9200 Aalborg SV
Product:	ROBERT®, 24-900-000
Medical device classification:	Class IIa, rule 9 according to Annex IV of the MDD
GDPR Conformity Assessment Route:	EU General Data Protection Regulation (GDPR)
<p>We herewith declare Life Science Robotics ApS is committed to protecting the data and information of our clients and candidates in accordance with EU General Data Protection Regulations (GDPR). We continue to monitor the guidance around GDPR compliance from privacy-related regulatory bodies and will adjust our plans accordingly if it changes.</p> <p>In our goal of always providing our customers with a safe and viable product we update and test our products to meet the high regulatory demands of medical device products, which also includes the monitoring of the performance and effect of our device.</p> <p>In detail this means, that the ROBERT® device can be equipped with the Data Collection Module, which not only serves to bring historic training data for comparison measures, for ease of use and for more evidence for the progression of the patient training. It also supports regulatory compliance by documenting the effectiveness and clinical effect of ROBERT®.</p> <p>Consequently, the Data Collection Module of ROBERT® will collect the following patient specific data:</p> <ul style="list-style-type: none"> - Unique ID, - Name (one-way encrypted by state of the art encryption methods), - Date of birth, - Medical condition relevant for ROBERT® (on a superficial level, i.e., “stroke”) and how severe the condition is (data is not exportable from device, only possible if Data Export Module is installed) <p>The data recorded by a specific ROBERT® is only stored on this specific device, and data can only be extracted by Life Science Robotics ApS personal, trained in the safe handling of patient data.</p> <ul style="list-style-type: none"> - We do not transfer to other data controllers. - We use Dropbox to store training data from ROBERT® on EU based servers. - No transfer of personal data to third countries takes place. <p>Information gathered through the ROBERT® Data Collection Module is stored in up to five years at Life Science Robotics ApS to adhere to the requirements in the EU Medical Device Regulation which requires manufacturers of medical devices to prove a clinical effect of their devices. Other than that, all data stored in the module itself that is older than 6 months is automatically deleted. When ROBERT® is detached and installed anew, all existing data in the module is also deleted.</p> <p>Any data obtained by Life Science Robotics ApS is only processed to document the effectiveness and clinical effect of ROBERT® in accordance with the requirements of the EU Medical Device Regulation, see GDPR Article 6(1)(c) and because it is our legitimate interest to conduct meaningful analysis of how our product works, see Article 6(1)(f). The interests of the data subject do not outweigh our interests since the data subject cannot be identified directly.</p>	
Place, Date of Issue:	Aalborg, 2021-11-22
Signature:	<div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  CEO, Keld Thorsen </div> <div style="text-align: center;">  CTO, Rune Kristensen </div> </div>