

**DECLARATION OF INTERESTS OF THE TOP-LEVEL MANAGEMENT OF A NOTIFIED BODY  
ACCORDING TO REGULATION (EU) 2017/745 (MDR) – ANNEX VII**

**Applicant Notified Body:** TÜV Rheinland Italia – Via Mattei, 3 – 20005 Pogliano Milanese (MI) – Italy

**Name:** Kirsten Raapke

**Role in the Notified Body top-level management:** President Board of Directors

Regulatory reference	Question	Your Answer	If Yes – Please describe the nature of the interest and specify the period
Reg. (EU) 2017/745 – Annex VII 1.2.3(a)	Are you currently involved in any design, manufacturing, installation, purchasing or maintenance activities related to medical devices?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
	Have you ever been involved in any of the above-specified activities, even if your involvement has been discontinued?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
	Are you or were you in the past the owner of any medical devices, except those used for personal purposes?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Reg. (EU) 2017/745 – Annex VII 1.2.3(b)	Did you ever represent any company or other party involved in the above-specified activities?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Reg. (EU) 2017/745 – Annex VII 1.2.3(c)	Did you ever engage in any activity that may conflict with TÜV Rheinland Italia independence of judgement or integrity in relation to conformity assessment activities	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Regulatory reference	Question	Your Answer	If Yes – Please describe the nature of the interest and specify the period
	<p>for which the designation application has been submitted?</p> <p><i>Such activities may include, but are not limited to:</i></p> <ul style="list-style-type: none"> <li>• <i>Ownership of a company or other entity that performs any design, manufacturing, installation, purchasing or maintenance activities related to medical devices</i></li> <li>• <i>Being a shareholder for any such company</i></li> <li>• <i>Taking part in any research project which received monetary or non-monetary support from a company or other entity involved in the above-specified activities</i></li> <li>• <i>Having any intellectual property (patents, trademarks, copyrights, including pending applications) related to medical devices</i></li> </ul>		
Reg. (EU) 2017/745 – Annex VII 1.2.3(d)	Have you ever been involved in the provision of consultancy services to manufacturers, authorized representatives or suppliers of medical devices?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Reg. (EU) 2017/745 – Annex VII 1.2.3(e)	Are you linked in any way to organizations which themselves provide consultancy services as referred above?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

Regulatory reference	Question	Your Answer	If Yes – Please describe the nature of the interest and specify the period
	<p><i>Examples of “being linked” include, but are not limited to:</i></p> <ul style="list-style-type: none"> <li>• <i>Ownership of a company or other entity that provides consultancy services, even if you are not directly performing any operational activity</i></li> <li>• <i>Being a shareholder for any such company</i></li> <li>• <i>Being a consultant for any such company</i></li> </ul>		
Reg. (EU) 2017/745 – Annex VII 1.2.5	Does or will your level of remuneration depend on the results of assessments carried out by TÜV Rheinland Italia as a Notified Body under Reg. (EU) 2017/745?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

I hereby declare that the above Declaration of Interests is truthful and complete to the best of my knowledge.

10/03/2022

