

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: Massimiliano Testi

Role in the Notified Body top-level management: Local Field Manager Medical

| 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? | □ Yes ⊠ No | |
| | Have you ever been involved in any of the above-specified activities, even if your involvement has been discontinued? | ⊠ Yes □ No | 1996-1998 in Company producing of disposable medical devices |
| | Are you or were you in the past the owner of any medical devices, except those used for personal purposes? | □ Yes ⊠ 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? | □ Yes ⊠ 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 | □ Yes ⊠ No | |



| Regulatory reference | Question | Your Answer | If Yes – Please describe the nature of the interest and specify the period |
|--|---|-------------|---|
| | for which the designation application has been submitted? Such activities may include, but are not limited to: Ownership of a company or other entity that performs any design, manufacturing, installation, purchasing or maintenance activities related to medical devices Being a shareholder for any such company Taking part in any research project which received monetary or nonmonetary support from a company or other entity involved in the above-specified activities Having any intellectual property (patents, trademarks, copyrights, including pending applications) related to medical devices | | |
| 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? | □ Yes ⊠ 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? | □ Yes ⊠ No | |

TÜV Rheinland Italia S.r.l.



| Regulatory reference | Question | Your Answer | If Yes – Please describe the nature of the interest and specify the period |
|---|---|-------------|---|
| | Examples of "being linked" include, but are not limited to: Ownership of a company or other entity that provides consultancy services, even if you are not directly performing any operational activity Being a shareholder for any such company Being a consultant for any such company | | |
| 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? | □ Yes ⊠ No | |

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

Date 10.03.2022

Signature