**Annex : List of recommended organizations**

These organizations have extensive knowledge of the ISO14971 (Application of risk management to medical devices) and ISO13485 (Medical devices — Quality management systems) standards and capable of designing and manufacturing according to these standards.

FAHMP recommends hospitals to contact these companies in priority.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Organisation** | **Contact** |  | **ISO 13485 or equivalent** | **Remark** |
| Materialise |  | [fightcovid@materialise.be](mailto:fightcovid@materialise.be) | Certified |  |
| 3D Side | Khanh Tran Duy | [ktd@3dside.eu](mailto:ktd@3dside.eu) | Certified |  |
| Spentys | Louis-Philippe Broze | [lp@spentys.com](mailto:lp@spentys.com) | Equivalent |  |
| Addiparts | Charles Demoulin | [c.demoulin@addiparts.com](mailto:c.demoulin@addiparts.com) | Certified |  |  |
| Cerhum | Gregory Nolens | [gregory.nolens@cerhum.be](mailto:gregory.nolens@cerhum.be) | Certified | Small batches (15-40 pieces/week) |
| CadSkills |  | [info@cadskills.eu](mailto:info@cadskills.eu) | Certified |  |
| 3D Systems | Jonas Van Vaerenberg | [jonas.vanvaerenbergh@3dsystems.com](mailto:jonas.vanvaerenbergh@3dsystems.com) | Certified |  |
| Sirris | Simon Vermeir | [Simon.Vermeir@sirris.be](mailto:Simon.Vermeir@sirris.be) | Equivalent | Part printing only if no capacity is available at commercial solution providers. |

If other organizations which follow the guidance are willing to be part of this list, please contact the Agency – [meddev@afmps.be](mailto:meddev@afmps.be) – subject: Guidelines 3D