MALTA MEDICINES AUTHORITY

P-LG01-04 Appendix 3 Version 01

Expert Form in the Field of Medical Device Regulatory Sciences

Expert Form (*Please note that ♦ indicates a mandatory field)*

Title

1. **♦ Family Name**

2. **♦ First Name**

3. **♦ Nationality**

4. **♦ Organisation/ Company Name and Professional Address**

5. **♦ Home address**

6. **♦ Business Phone No (including International Code)**

7. **♦ Business email address**

8. **♦ Passport number**

9. **♦ Qualifications - Degrees, Diplomas and Professional Affiliations** *(Please give a brief description of your qualification. A Curriculum Vitae (CV) must be attached.)*

10. **♦ Present position and time spent in current assignment** *(Please give a brief description of your current job position and indicate the year that you started your current assignment.)*

11. **♦ General Category of Activities - Medical Device Evaluation** (*Please tick the relevant boxes if you possess relevant expertise)*

☐ **Medical Devices according to MDR 2017/745 Regulation (EU)**

☐ Active device

☐ Accessory for a medical device

☐ CMR Substances

☐ Containing latex

☐ Contains substances considered medicinal products derived from human blood or plasma

☐ Custom-made device

☐ Endocrine disrupting substances

☐ IIb Implantable well-established technology

☐ Implantable devices

☐ Intended to administer/ remove a medicinal substance

☐ Invasive device

☐ Made to order Rigid Gas Permeable (RGP) contact lenses

☐ Made to order soft contact lenses

☐ Measuring function

☐ Needs Sterilisation

☐ Orthopaedic

☐ Procedure Pack which is a device in itself

☐ Ready-made reading spectacles

☐ Reusable surgical instrument

☐ Software

☐ Spectacle frames

☐ Spectacle lenses

☐ Standard Rigid Gas Permeable (RGP) contact lenses

☐ Standard soft contact lenses

☐ Sterile

☐ System which is a device in itself

☐ Tissues or Cells from animal origin

☐ Tissues or Cells from human origin

☐ **In-Vitro Diagnostic Devices according to IVDR 2017/746**

☐ Accessory for an in vitro diagnostic medical device

☐ Cells or Substances of microbial origin

☐ Companion diagnostic

☐ Instrument

☐ Intended for near-patient testing

☐ Intended for self-testing

☐ KIT

☐ Needs Sterilisation

☐ New Device

☐ Professional Testing

☐ Reagent

☐ Software

☐ Sterile

☐ Tissues or Cells from animal origin

☐ Tissues or Cells from human origin

☐ Other (Please specify): ……..

12. Are you a member of staff of a competent authority?

☐ Yes

☐ No

13. Are you an external expert? (e.g. medical device economic operator/ entity, member of staff of another organisation, hospital, University etc)

☐ Yes

☐ No

If yes, please specify:

14. Languages known

Please specify level, including your mother tongue	R	W	S
R: Read, W: Written, S: Spoken, P: Poor, A: Average, G: Good, E: Excellent			

15. Areas of Expertise (*Please tick the relevant boxes if you possess relevant expertise)*

☐ Clinical Evaluation / Performance Evaluation

☐ Clinical Investigations / Performance Studies

☐ Post-market clinical follow-up

☐ Biological and Chemical Safety

☐ Mechanical, Electrical, or Software Engineering - Different device technologies, design and manufacturing processes

☐ IT/ Data security expert for software as a medical device

☐ Sterilisation processes. Specify which process:

- ☐ aseptic processing
- ☐ ethylene oxide gas sterilisation (EOG)

☐ low temperature steam and formaldehyde sterilisation

☐ moist heat sterilisation

☐ radiation sterilisation (gamma, x-ray, electron beam)

☐ sterilisation with hydrogen peroxide

☐ sterilisation with liquid chemical sterilising agents

☐ thermic sterilisation with dry heat

☐ Other sterilisation processes, indicate: ……

☐ Products containing viable biological material or viable organisms of another origin

☐ Devices manufactured utilising tissues or cells of animal origin or their derivatives, such as from TSE susceptible species

☐ Packaging and Stability

☐ Usability and Human Factors (a design process focused on understanding user-device interactions to minimize errors and ensure safe, effective use)

☐ Integrating Nanomaterials

☐ Physico-chemical characterisation including microbiological, biocompatibility, mechanical, electrical, electronic or non-clinical biological and toxicological testing

☐ Risk management

☐ Other (Please specify): ……..

16. Therapeutic areas (*Please tick the relevant boxes if you possess relevant expertise)*

☐ Orthopaedics, traumatology, rehabilitation, rheumatology

☐ Circulatory system

☐ Neurology

☐ Respiratory system, anaesthesiology, intensive care

☐ Endocrinology and diabetes

☐ General and plastic surgery and dentistry

☐ Obstetrics and gynaecology, including reproductive medicine

☐ Gastroenterology and hepatology

☐ Nephrology and urology

☐ Ophthalmology

☐ Paediatrics and rare diseases

☐ Other (Please specify): ……..