|  |  |
| --- | --- |
| Company name: |       |
| Company address: |       |

Prerequisite for the validity extension of EC Directive certificates is a valid EN ISO 13485 certificate, issued by TRLP. Please indicate the certificate registration number:

|  |  |
| --- | --- |
| SX       | Expiry date:       |

Please list all quality management system based EC Directive certificate(s) to be extended:

|  |  |
| --- | --- |
| EC Certificate Registration No.: | Expiry Date: |
|       |       |
|       |       |

**I confirm the following prerequisites
for an AIMDD/MDD/IVDD Certificate Validity Extension:**

* No substantial changes in regard to the quality management system
* No changes in product scope
* MDD/AIMDD: A new ”Product list and application” (MS-0023786) with full scope of products currently covered by the conformity assessment procedure and/or
IVDD: A new “Application for EC conformity assessment procedure” (MS-0023798) and “Product description form IVDD” (MS-0023783) (please attach)

**Please note:**

* Please submit this certificate validity extension information at least six months prior to the expiration of your certificate. In case the duly completed documents for the certificate validity extension are not submitted in time, a certificate validity extension without gap to the former certificate is at risk.
* In case of changes please refer to Notified Body Recommendation NB-MED/2.5.2/Rec2, Rev. 8, and apply for the change request as a separate application.

|  |  |
| --- | --- |
| Date/Signature |       |
| Name of contact person |       |