

Guide to Electronic Submissions – Medical Devices



1 SCOPE

This guidance applies to certain applications for medical devices. These include designation applications for conformity assessment bodies, clinical investigations and compassionate use applications. This guidance will be updated should other processes be required to utilise CESP for submissions to the Health Products Regulatory Authority (HPRA).

2 INTRODUCTION

The HPRA strongly recommends electronic-only submissions through CESP (Common European Submission Platform, available on the following website <https://cespportal.hma.eu>

If companies have problems with submitting electronic applications using CESP, they should contact the HPRA at devices@hpra.ie to discuss their situation before making an application.

3 ELECTRONIC SUBMISSIONS

3.1 Definitions

3.1.1 CESP

CESP - the Common European Submission Platform is a simple and secure mechanism for the exchange of submission information between applicants and Competent Authorities and Authorities responsible for Notified Bodies.

3.2 Guidance

Guidance for industry on submissions through CESP is available on the CESP website www.cesp.hma.eu/

4 REQUIREMENTS FOR CESP

4.1 CESP submissions

Please be aware of the following while submitting through CESP:

- Do not drop over the delivery file until the entire submission has fully uploaded to CESP.
- Please refer to our National Requirements which are indicated on the Contacts tab of the CESP Platform prior to submitting documentation.
- CESP supports the upload of zip files using the following software only: Winzip and Microsoft Compressed File Format.
- Where there are large numbers of products, sequences and procedures, please use an identification matrix that can be filtered to allow ease of tracking of applications.

Delivery file:

- Must not be renamed or re-used.
- Ensure the type of submission is correctly identified.
- Ensure the appropriate category on the dropdown list is selected.
- Specify the zip software used for compression.

4.2 Additional information to be included with the submission

Note: The HPRA does not accept password protected submissions.

5 CONTACT POINTS

If you have a specific query regarding CESP submissions to the HPRA, please contact cesp@hma.eu. For information regarding CESP and registration please go to the CESP website www.cesp.hma.eu/. For all other queries relating to medical device applications, please contact devices@hpra.ie