Question for written answer E-004767/2013 to the Commission Rule 117 Anna Rosbach (ECR)

Subject: Translation of information on medical devices

EU medical devices legislation is marked by differences between the requirements that exist in individual Member States and in how each Member State implements the legislation.

In light of the above, could the Commission answer the following:

- 1. What are the rules governing the translation of software for use with, or forming part of, medical devices in each Member State?
- 2. Does the Commission foresee any changes to these rules?