Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

## ANNEX III

## EC DECLARATION OF CONFORMITY

4. The manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured.

The system shall address:

- the organisational structure and responsibilities,
- the manufacturing processes and systematic quality control of production,
- the means to monitor the performance of the quality system.