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 IV

CONFORMITY ASSESSMENT PROCEDURE – PRODUCTS

1. Internal production control

Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4 of this Annex, and ensures and declares on its sole responsibility that the product concerned satisfy the appropriate requirements of this Directive.

2. Technical documentation

The manufacturer shall establish the technical documentation. The technical documentation shall make it possible to assess the conformity of the product to the relevant accessibility requirements referred to in Article 4 and, in case the manufacturer relied on Article 14, to demonstrate that relevant accessibility requirements would introduce a fundamental alteration or impose a disproportionate burden. The technical documentation shall specify only the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product.

The technical documentation shall, wherever applicable, contain at least the following elements:

(a) a general description of the product;

(b) a list of the harmonised standards and technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the relevant accessibility requirements referred to in Article 4 where those harmonised standards or technical specifications have not been applied; in the event of partly applied harmonised standards or technical specifications, the technical documentation shall specify the parts which have been applied.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the products with the technical documentation referred to in point 2 of this Annex and with the accessibility requirements of this Directive.

4. CE marking and EU declaration of conformity

4.1. The manufacturer shall affix the CE marking referred to in this Directive to each individual product that satisfies the applicable requirements of this Directive.

4.2. The manufacturer shall draw up a written EU declaration of conformity for a product model. The EU declaration of conformity shall identify the product for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

5. Authorised representative

The manufacturer’s obligations set out in point 4 may be fulfilled by its authorised representative, on its behalf and under its responsibility, provided that they are specified in the mandate.