

SCHEDULE 2

Regulation 19

Fees in connection with the designation of notified bodies

Table 1**Application fees**

<i>Application</i>	<i>Fee</i>
1. For initial designation submitted under Article 38	£8,252
2. For initial designation re-submitted under Article 38 where the changes from the immediately preceding application are limited to addressing the grounds on which the Secretary of State previously refused the application	£2,063
3. For reassessment under Article 44(10)	£8,252
4. For an extension of the scope of the designation under Article 46(1)	£6,504

Table 2**Fees for assessments and reviews**

<i>Activity</i>	<i>Fee</i>
1. On-site assessment under Article 39(4) in connection with an application for initial designation under Article 38, or an application for reassessment under Article 44(10)	£15,904
2. On-site audit as part of an annual reassessment under Article 44(4)	£10,160
3. Observed audit of notified body personnel under Article 44(5)	£4,404
4. On-site assessment of a subsidiary	£3,876
5. 'For-cause' review under Article 44(7) to—	(a) £2,586
(a) review assessments by the notified body, including clinical evaluation documentation;	(b) £3,876
(b) otherwise verify compliance with the requirements of Regulation (EU) 2017/745 or address a particular issue	