Appendix 2 – List of External Documents

No.	Code	Document name	[illegible]	[illegible]	[illegible]	[illegible]
1	*C2733*	*Agreement for purchasing of contact lenses*	[illegible]	[illegible]	[illegible]	[illegible]
2	*ISO 20714:2021*	*Information supplied by the manufacturer*	[illegible]			
3	*ISO 13485:2016*	*Medical devices — Quality management systems — Requirements for regulatory purposes*	[illegible]			
4	*ISO 14971:2019*	*Medical devices — Application of risk management to medical devices*	[illegible]			
5	*ISO 10993-5:2009*	*Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*	[illegible]			
6	*MDCG 2020-7*	*Guidance on PMCF plan template*	[illegible]			
7	*MDCG 2020-6*	*Guidance on sufficient clinical evidence for legacy devices*	[illegible]			
8	*MDCG 2020-5*	*Guidance on clinical evaluation – Equivalence*	[illegible]			

Commented [AES1]: If the organization uses electronic [illegible]

Commented [AES2]: If you want to find out more about document control, see this article: [illegible]

Commented [AES3]: Use the code, name and version that is given by the external owner of the document. [illegible]

Commented [AES5]: Include document version where [illegible]

Commented [AES6]: External document owners may include [illegible]

Commented [AES4]: E.g., national regulation, harmonized [illegible]

Commented [AES7]: Listed items are just the examples of [illegible]

9	*MDCG 2019-15 rev.1*	*Guidance notes for manufacturers of class I medical devices*				
10	*MDCG 2020-2 rev.1*	*Class I transitional provisions under Article 120 (3 and 4) – (MDR)*				

[job title]
[name]

[signature]

Commented [AES8]: Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.