1. ------IND- 2019 0600 D-- EN- ------ 20191209 --- --- PROJET

State Ordinance amending the State Ordinance  
on the prevention of communicable diseases (Hygiene Regulation [HygieneVO])[[1]](#footnote-1)  
of

On the basis of § 17(4) of the Protection against Infection Act [Infektionsschutzgesetz] of 20 July 2000 (Federal Law Gazette I p. 1045), last amended pursuant to Article 18a of the Regulation of 9 August 2019 (Federal Law Gazette I p. 1202), in conjunction with § 1(1) of the Ordinance on the Transfer of Authorisations under the Protection against Infection Act of 22 February 2001 (Official Gazette Schl.-H p. 35), department names last replaced by Article 21 of the Regulation of 16 January 2019 (Official Gazette Schl.-H p. 30), the Ministry of Social Affairs, Health, Youth, Family and Senior Citizens decrees the following:

 1. § 3(1) shall be worded as follows:

‘(1) It must be possible to clean with a damp cloth and disinfect the inventory in all rooms intended for diagnosis and therapy in which contamination with bodily fluids and other materials containing pathogens is to be expected. All disinfectants used must be suitable for preventing infection at medical facilities and proven to be effective in doing so. The effectiveness for the effective range required in each case must be at least bactericidal, yeasticidal and, to a limited extent, virucidal, and potentially also fungicidal, tuberculocidal, mycobactericidal and effective against bacterial spores. The effectiveness must be proven by at least two independent expert reports with the corresponding test reports. The effectiveness shall be deemed to be confirmed if the tests were carried out by testing laboratories independent of the manufacturer and the test reports are confirmed by independent experts in a scientifically based evaluation. The test laboratories shall have the necessary expertise, which can be demonstrated by such means as accreditation as per DIN ISO EN 17025:2018-03 of March 2018. For example, the test method in question shall be validated by interlaboratory tests in order to take into account statistical variability, which includes at least two required repeated tests. Tests performed in accordance with the technical specifications of another Member State of the European Union or of Turkey or of another State party to the Agreement on the European Economic Area shall be recognised as being equivalent if the technical specifications equally achieve the level of protection required under the second sentence on a permanent basis.’

2. § 5 is worded as follows:

§ 5   
Regulatory offences

(1) A breach of the regulations within the meaning of § 73(1a)(6) of the Protection against Infection Act [Infektionsschutzgesetz] is committed by anyone who wilfully or negligently

1. fails to carry out or insufficiently carries out cleaning, disinfection or sterilization by means of a suitable procedure or fails to store the devices in such a way that they are protected against contamination contrary to § 3,
2. uses disinfectants and disinfection procedures other than those referred to in § 3,
3. fails to dispose of the devices and other items specified therein in suitable containers contrary to § 4,
4. fails to comply with an obligation to tolerate or an obligation to provide information in accordance with § 73(1a)(3) and (4) of the Protection against Infection Act or the obligation to submit documents, in particular hygiene plans, in accordance with § 73(1a)(5) of the Protection against Infection Act

or wilfully or negligently acts in contravention of a corresponding, enforceable instruction in accordance with § 17(1) of the Protection against Infection Act.

3. This Ordinance shall enter into force on the day following its promulgation.

The above Ordinance is hereby issued and promulgated.

Kiel,

Dr. Heiner Garg

Minister of Social Affairs, Health, Youth,   
Family and Senior Citizens

1. Notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, p. 1). [↑](#footnote-ref-1)