EC DECLARATION OF CONFORMITY

(Medical Device Directive 93/42/EEC Annex VII)

Orkla Care AB

Hereby declare that the Medical Device products listed below conform to the relevant provisions of the Swedish Law regarding Medical Devices (1993:584) and the current version of LVFS 2003:11, which is the Swedish implementation of the Medical Device Directive 93/42/EEC including amendments to date.

For devices class I sterile as verified by our Notified Body, # 0413 according to Medical Device Directive 93/42/EEC, Annex II, EC Certificate A2 41315275-06.

REF	Name of product		Medical Device Class	GMDN
7251	Cederroth	Eye Wash 500mL	Is	11655
7221	Cederroth	Eye Wash Pocket Model	Is	11655
7255 New REF (*): 51011042	Cederroth	Eye Wash in portable case	Is	11655
725200	Cederroth	Eye Wash 2x500mL	Is	11655

(*) We hereby confirm that the change made to the Declaration of Conformity is only of administrative nature and does not have an impact on the design or the intended purpose for the products and is thereby regarded as non-significant in the meaning av MDR Article 120(3). DoC Cederroth Eye Wash_EN_2021-04-30 was drawn up before 26 May 2021.

Solna 2024-10-25

Johanna Brinck

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