

To whom it may concern

18 December 2025

Declaration letter

Coloplast A/S hereby declares that the medical devices listed below are Risk Class I devices, non-measuring, non-sterile and the participation of a notified body is therefore not required for the purposes of conformity assessment. Therefore, the notified body certificate was not issued in view of the above.

Medical devices concerned:

Name	Description	Code
SenSura Mio irigační souprava	NÁDRŽKA NA VODU, ZAVÁDĚcí KONUS, IRIGAČNí SÁČEK 30 KS, KRYTKA 4 KS, 11751	11751
SenSura Mio irigační sáček	IRIGAČNí SÁČEK, JEDNODÍLNÝ, 11750	11750



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