

Change Notification

Change No.	1168 1169 1189	Issue date	27.09.2024	Revision	01
Affected products	WM090TD / WM100TD / WM110TD / WM120TD				
Device Trade Name	prisma SMART, prisma SOFT, prisma SMART plus, prisma SMART max, prisma SOFT plus, prisma SOFT max prisma20C, prisma20A, prismaCR, prisma25S, prisma25S-C, prisma25ST, prisma30ST, prisma30ST-HFT, prismaLAB prisma VENT30/ prisma VENT30-C/ prisma VENT40, TIVAN 30 / 30-C / 40, Prisma Comfort40 prisma VENT50, prisma VENT50-C, TIVAN 50				
Article No.	All Article numbers of the above listed device trade names.				

This is to inform about the following change of the above mentioned products:

Description of change

The foams for sound insulation in WM090TD/ WM100TD/ WM110TD /WM120TD are replaced with an alternative foam from an approved and already used supplier (**s 47**). The newly implemented foams have undergone extensive testing according to our validation and verification processes to ensure they meet the required standards. This foam change does not impact device specifications or safety or performance of the products. Compliance with all regulatory requirements remains unchanged. Following the risk assessment, no new risks were identified.

Sound insulation foams before change	Sound insulation foams after change
Surface sealed polyether based polyurethane foam (s 47)	Surface sealed polyether based polyurethane foam (s 47)
Polyurethane Foam on Polyester base (s 47)	Polyether based polyurethane foam (s 47)

Reason for change

The foam replacement was carried out due to the potential risk of supply shortages from the the original foam suppliers. To ensure continuous supply and consistent product quality, a proactive decision was made to switch to an alternative foam solution, which has been thoroughly tested, validated and verified. The safety and performance characteristics of the products remain unaffected by this change.

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Date, Signature