Smiths Medical Czech Republic, a.s.
Olomoucká 306
75301 Hranice
Tel: +420 581 671 123
www.smiths-medical.com

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Notification of suspension of CE mark

To whom it may concern,

On 6 October 2021 Smiths Medical initiated a voluntary Field Safety Corrective Action regarding the below device due to the potential for aluminum ion leaching into warmed fluids. Aluminum ion leaching has been identified in the disposables sets used with these systems:

Trade name	Level 1® H-1000 Fast Flow Fluid Warmer
Legal Manufacturer	Smiths Medical ASD, INC, 6000 Nathan Lane North, MN 55442 Minneapolis
Authorized Representative	Smiths Medical Czech Republic a.s., Olomoucká 306, 75301 Hranice
Generic name/ kind of device	Fluid warmer, high-flow
NCA report reference no	sukls233623/2021
Eudamed reference:	INC-CZ-21-11-000006
Manufacturer ref. number	3012307300-08/09/2021-011-R

Smiths Medical has put the above-mentioned items on ship hold as a result of the Field Safety Notices, which included recommendations to users of these devices in the EU based on feedback from Competent Authorities and Smiths Medical's Notified Body.

Smiths Medical would like to inform you that following the outcome of the technical file audit for the Level 1 Fast Flow Fluid Warmers and the Normothermic Administration Sets and Accessories, our Notified Body, BSI, has processed the scope restriction for Annex II.3 CE 669121 certificate to suspend the following products:

Assurance CE Number	**Product Model Name**	**Product Model Number**
CE 669121	Level 1 Fluid Warmer	H-1000
CE 669121	Level 1 Fluid Warmer Systems	H-1000 H-1025 H-1200
CE 669121	Level 1 Normothermic I.V. Fluid Administration Set	D-100 D-300 D-50 D-60HL DI-100 DI-300 DI-50 DI-60HL D-70 DI-70
CE 669121	Pressure Chambers	7204036 7204017

		7204031 7204012 7204018 7204016 7204034 7204030 7204074 7204019 7204066 7204020
CE 669121	High-Flow 3 Way Stopcock	SC-3
CE 669121	High Flow Extension Line	X-36
CE 669121	High Flow Extension with Injection Site r	Y-INJ
CE 669121	High Flow Y-Type Extension	Y-30
CE 669121	Gas Vent/Filter Assembly	F-10 F-30

An updated version of the above mentioned FSN will be circulated to European Competent Authorities 1st February 2022. In parallel, a notification of the above will be sent out to Smiths Medical's customers. Smiths Medical strongly reminds users to follow instructions on the current, above mentioned FSN.

Smiths Medical intends to leave the existing installed product base with customers as the Fluid Warmer and Administration Sets are a fully dedicated system. Without access to the Administration Sets, there is no additional risk for the use of remaining Fluid Warmers. The Notified Body has given Smiths Medical a 6-month timeframe for remediation.

The ship hold currently in place has not been amended in any way. Any countries with issued ship hold derogations have been put back onto ship hold.

If you have any questions, we are available to discuss the above on a call with you.

Best regards

Smiths Medical