EUROPEAN MEDICAL DEVICE REGULATION

Declaration of Conformity

As Legal Manufacturer, we

3M Company
Single Registration Number: US-MF-000014086
2510 Conway Ave. St. Paul, MN 55144 USA

hereby declare under our sole responsibility that the following CE marked device(s)

Trade Name	3M™ Curos™ Stopper Disinfecting Caps for Open Female Luers 3M™ Curos™ Stopper Disinfecting Cap Strips for Open Female Luers
Intended Purpose	The 3M™ Curos™ Stopper Disinfecting Caps for Open Female Luers and 3M™ Curos™ Stopper Disinfecting Cap Strips for Open Female Luers is intended for use only on open female luers such as catheter hubs and stopcocks. After application, it acts as an external disinfecting cleaner prior to I.V. access and as a cover between line accesses. In one (1) minute after application the cap will disinfect the connection and protect from contamination between accesses for up to seven (7) days if not removed. The effectiveness of the cap was tested in vitro against *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Candida glabrata*, and *Candida albicans* and was found to have >4 log reduction. This cap may be used in the home or healthcare facility.
Reference	CSV1-270R CSV5-250R CSA1-270R CSA5-250R
Basic UDI-DI	06082238401010000000076AT

are classified per rule 16 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class IIa devices in accordance with Annex XI Part A and all other applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

This declaration is made based on the quality assurance certificate
EC Certificate Number: MDR 725202
Issued by: BSI, 2797

The Authorized European Representative for the concerned device(s) is

3M Deutschland GmbH
Health Care Business
Single Registration Number: DE-AR-000011642
Carl-Schurz-Str. 1
41453 Neuss, Germany

Dianne Gibbs

14 July 2022

Dianne Gibbs, RAC
Regulatory Affairs Director
3M Medical Solutions Division, 3M Company
2510 Conway Ave. St. Paul, MN 55144 USA

Location/Date