

EUROPEAN MEDICAL DEVICE REGULATION

Declaration of Conformity

As Legal Manufacturer, we

3M Company Single Registration Number (TBD) 2510 Conway Ave. St. Paul, MN 55144 USA

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

Trade Name*	FUTURO™ Tennis Elbow Strap
Intended Purpose	To support stiff, weak or injured elbow and forearm
Reference	45975DABI, 45975NORD, 45975SPEI
Basic UDI-DI	06082238401050000000022DY

are classified per rule 1 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class I devices in accordance with all applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

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

3M Deutschland GmbH Health Care Business Single Registration Number (TBD) Carl-Schurz-Str. 1 41453 Neuss, Germany

Bryan Becker, Division Quality and Regulatory Leader

3M Company

2510 Conway Ave. St. Paul, MN 55144 USA

3M and FUTURO are trademarks of 3M.

Issued to Authorized Representative (EC REP)



EUROPEAN MEDICAL DEVICE REGULATION

Declaration of Conformity

As Legal Manufacturer, we

3M Company Single Registration Number (TBD) 2510 Conway Ave. St. Paul, MN 55144 USA

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

Trade Name*	FUTURO™ Tennis Elbow Strap
Intended Purpose	To support stiff, weak or injured elbow and forearm
Reference	45975DABI, 45975NORD, 45975SPEI
Basic UDI-DI	06082238401050000000022DY

are classified per rule 1 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class I devices in accordance with all applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

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

3M Deutschland GmbH Health Care Business Single Registration Number (TBD) Carl-Schurz-Str. 1 41453 Neuss, Germany

Bryan Becker, Division Quality and Regulatory Leader

3M Company

2510 Conway Ave. St. Paul, MN 55144 USA

3M and FUTURO are trademarks of 3M.