CONFIDENTIAL

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DECLARATION OF CONFORMITY

Legal Manufacturer and Manufacturing Site:
Teleflex Medical Sdn. Bhd.
Lot PT 2577, Jalan Perusahaan 4,
34600 Kamunting, Perak, Malaysia

Authorized Representative:
Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Place of Issuance: Teleflex Medical Sdn. Bhd.

We hereby declare that under our sole responsibility the attached list of products meet all applicable provisions of the Council Directives 93/42/EEC. All supporting documentation are retained at the premises of the manufacturer and may be accessed, where appropriate, directly from the manufacturer.

Notified Body:	**DEKRA CERTIFICATION GmbH** Handwerkstraße 15 D-70565 Stuttgart, Germany
Registration No.:	50076-16-08 (MDD 93/42/EEC, Annex II)
Notified Body ID-number:	0124
Expiry Date:	26.05.2024

Approval

Function	Name	Approval	Date of Issuance
Originator	Siti Nur Atikah Idayu Bt Norzali	Ayu	11 Feb 2020
Regulatory Affairs	Chuah Siew See		11 Feb 2020
Quality Assurance	Lau Yee Fan		19 FEB 2020

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Device Description	Catalog no.	Size	Class	Rule	GMDN	Conformity Pathway	MD Code	Date CE mark affixed
Hudson RCI® Tracheostomy Adaptor	2415-01	N/A	IIa	2	35178	Annex II	MD 0101	17 Jan 2018

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