


## PART A – Declaration

INFORMATION ABOUT THE MANUFACTURING HEALTH INSTITUTION	
<b>Name</b>	Kent & Medway Communication Assistive Technology (KM CAT) Department of Medical Physics & Clinical Engineering East Kent Hospitals University NHS Foundation Trust
<b>Address</b>	Kent & Canterbury Hospital Ethelbert Road Canterbury CT1 3NG Department of Medical Physics & Clinical Engineering
<b>Name of contact</b>	Claire Garrett
<b>Job Title</b>	Clinical Scientist & Deputy Head of KM CAT
<b>Department</b>	Department of Medical Physics & Clinical Engineering
<b>Contact telephone number</b>	01227 864084 (adult team) 01233 629859 (children's team)
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DECLARATION	
<p>Devices listed in part B are manufactured or modified and used by this health institution and meet the relevant General Safety and Performance Requirement set out in Annex I of the regulations on IVD (2017/746)/ MD (2017/745).</p> <p>These devices are manufactured in accordance with our Technical Documentation.</p> <p>Further information concerning the use of exempt device will be provided to MHRA upon request. I understand that MHRA may need to inspect these activities.</p>	<div style="text-align: center;"> ..... Signed on behalf of the organisation</div> <div>Name     Ladan Najafi Date     27/10/22</div>

## **PART B – Listing of exempt devices**

Coding System:

BS EN ISO 9999:2022 Assistive products. Classification and terminology

<b>Device</b>	<b>Code</b>
KM CAT Key Guard	22 21 09 Accessories to assistive products for face-to-face communication – Dialogue Units
KM CAT Bracket	22 21 09 Accessories to assistive products for face-to-face communication – Dialogue Units
KM CAT Blocks, Pads & Wedges	22 21 09 Accessories to assistive products for face-to-face communication – Dialogue Units
KM CAT Tray	22 21 09 Accessories to assistive products for face-to-face communication – Dialogue Units
KM CAT Enclosure	22 21 09 Accessories to assistive products for face-to-face communication – Dialogue Units
Other Accessories to Communication Aids	22 21 09 Accessories to assistive products for face-to-face communication – Dialogue Units