

## Device Schedule: Article 22.3 Systems and Procedure Pack

| <b>Device(s)</b>                                                                                                                                                                                       | <b>Highest Risk Classification within the System or Procedure Pack</b> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|
| Gastrostomy Feeding Tube Procedure Packs                                                                                                                                                               | Class IIb                                                              |
| For Systems and Procedure Packs under Article 22.3, the Notified Body conformity assessment is limited to the aspects relating to ensuring sterility until the sterile packaging is opened or damaged. |                                                                        |