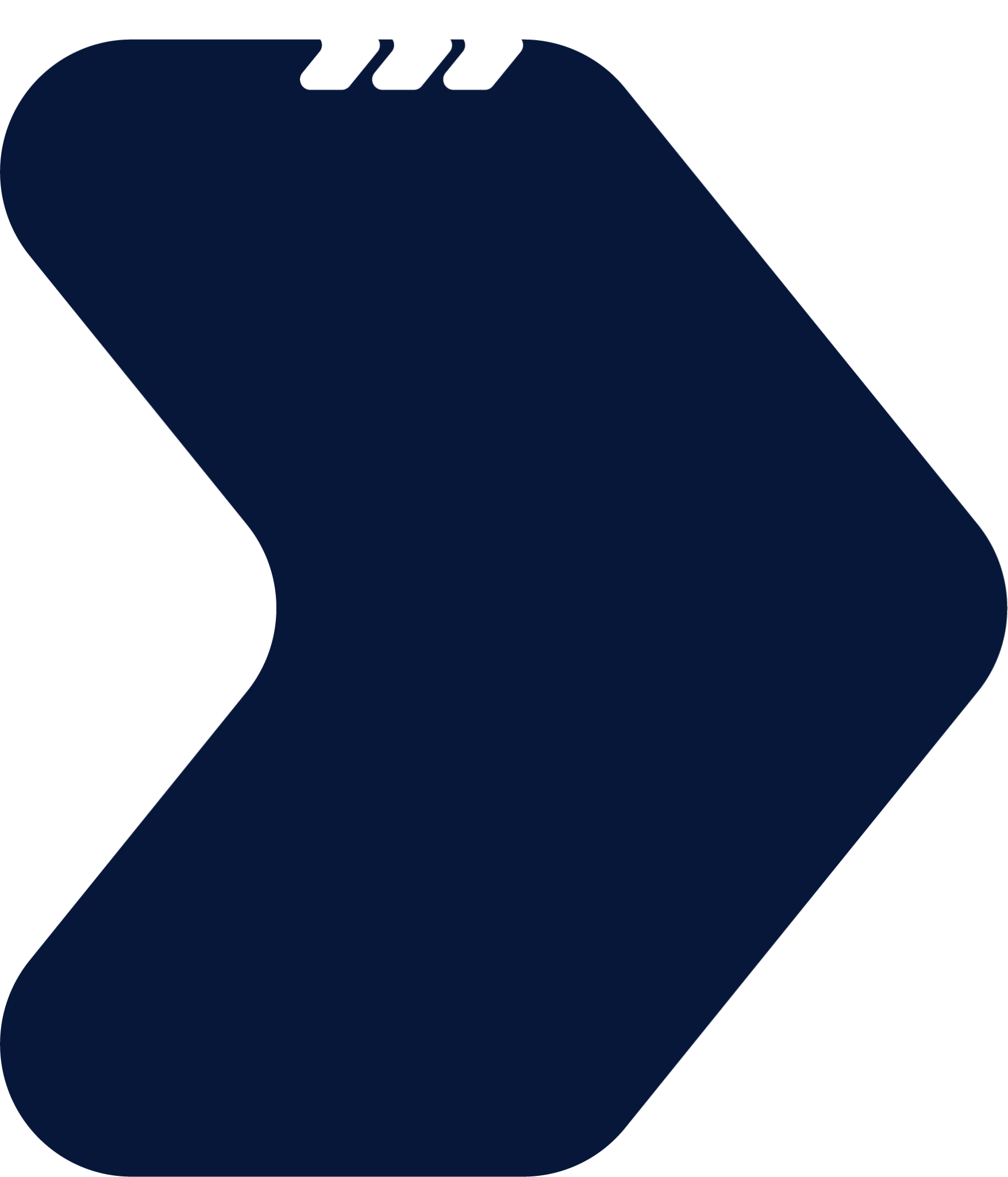


# Free MDR Labelling Requirements Identifier Tool by Trinzo

The increase in requirements and any associated labelling changes brought about by the EU MDR will have varying levels of cost and resourcing implications for you as a manufacturer.

The below table can be used as a high level guide to indicate what requirements of GSPR 23 might apply to your device. However, accurate and compliant labelling is essential, so it’s important to carefully consider all the requirements of GSPR 23 in relation to your speciﬁc device, ensuring that all applicable components are present on your label and in your instructions for use.



| **GSPR** | **Applicable to:** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **All**  **Devices** | **Sterile/ to be**  **sterilised** | **Single- use** | **Reusable** | **Custom- made** | **Implantable** | **Radiation emitting** | **Electronic** |
| **23.1 (a)** | ✔ |  |  |  |  |  |  |  |
| **(b)** | ✔ |  |  |  |  |  |  |  |
| **(c)** | ✔ |  |  |  |  |  |  |  |
| **(d)** | ✔ |  |  |  |  |  |  |  |
| **(e)** | ✔ |  |  |  |  |  |  |  |
| **(f)** | ✔ |  |  |  |  |  |  |  |
| **(g)** | ✔ |  |  |  |  |  |  |  |
| **(h)** | ✔ |  |  |  |  |  |  |  |
| **23.2 (a)** | ✔ |  |  |  |  |  |  |  |
| **(b)** | ✔ |  |  |  |  |  |  |  |
| **(c)** | ✔ |  |  |  |  |  |  |  |
| **(d)** | ✔**1** |  |  |  |  |  |  |  |
| **(e)** | ✔**1** |  |  |  |  |  |  |  |
| **(f)** | ✔**1** |  |  |  |  |  |  |  |
| **(g)** | ✔ |  |  |  |  |  |  |  |
| **(h)** | ✔ |  |  |  |  |  |  |  |
| **(i)** | ✔ |  |  |  |  |  |  |  |
| **(j)** | ✔ |  |  |  |  |  |  |  |
| **(k)** | ✔ |  |  |  |  |  |  |  |
| **(l)** |  | ✔ |  |  |  |  |  |  |
| **(m)** | ✔ |  |  |  |  |  |  |  |
| **(n)** |  |  | ✔ |  |  |  |  |  |
| **(o)** |  |  | ✔ |  |  |  |  |  |
| **(p)** |  |  |  |  | ✔ |  |  |  |
| **(q)** | ✔ |  |  |  |  |  |  |  |
| **(r)** | ✔**1** |  |  |  |  |  |  |  |
| **(s)** |  |  |  |  |  | ✔ |  |  |

*1 where applicable | 2 Professional users | 3 Lay users*

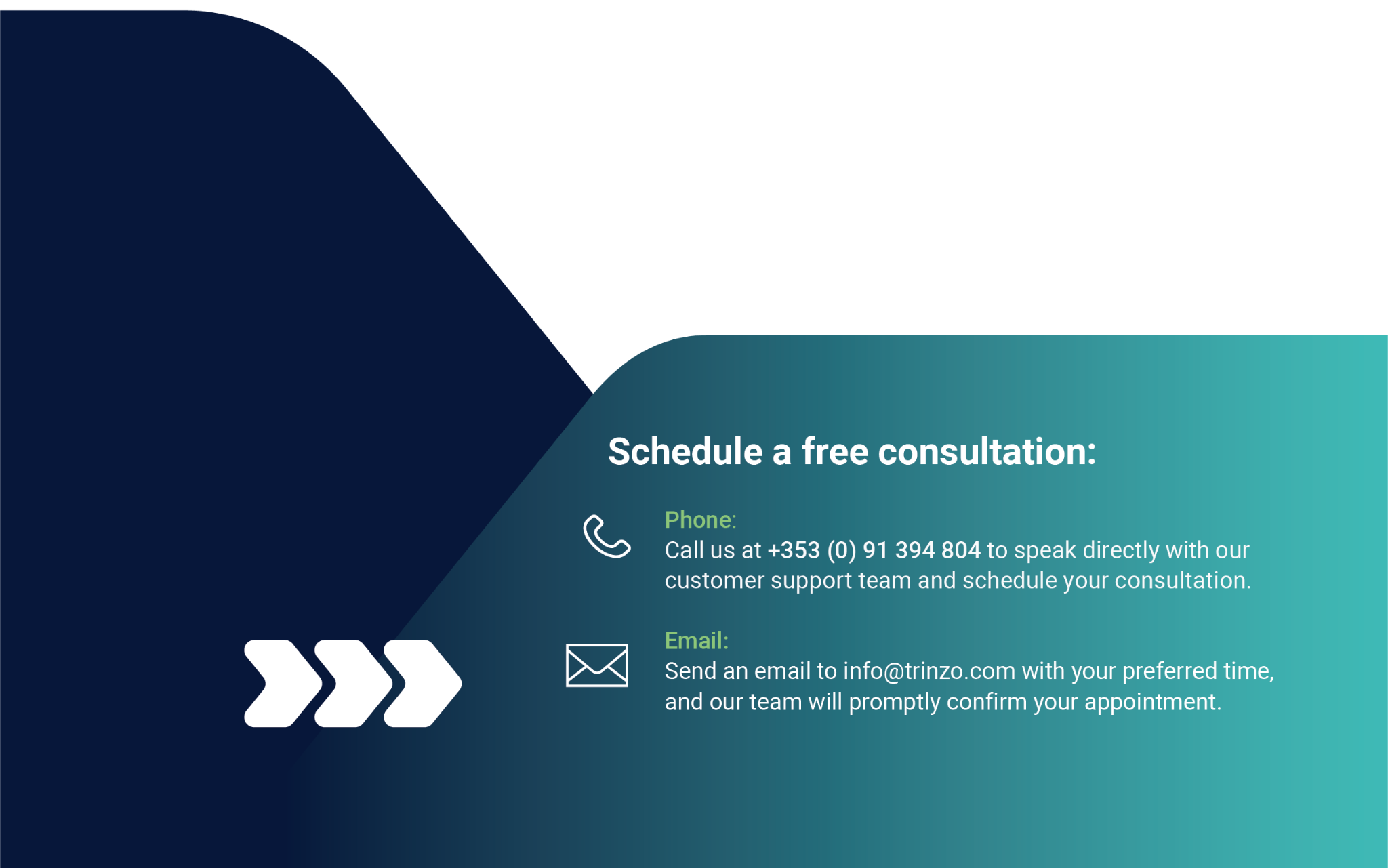
| **GSPR** | **Applicable to:** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **All devices** | **Sterile/ to be**  **sterilised** | **Single- use** | **Reusable** | **Custom- made** | **Implantable** | **Radiation emitting** | **Electronic** |
| 23.3 (a) |  | ✔ |  |  |  |  |  |  |
| (b) |  | ✔ |  |  |  |  |  |  |
| (c) |  | ✔ |  |  |  |  |  |  |
| (d) |  | ✔ |  |  |  |  |  |  |
| (e) |  | ✔ |  |  |  |  |  |  |
| (f) |  | ✔ |  |  |  |  |  |  |
| (g) |  | ✔ |  |  | ✔ |  |  |  |
| (h) |  | ✔ |  |  |  |  |  |  |
| (i) |  | ✔ |  |  |  | ✔ |  |  |
| (j) |  | ✔ |  |  |  |  |  |  |
| 23.4 (a) | ✔ |  |  |  |  |  |  |  |
| (b) | ✔ |  |  |  |  |  |  |  |
| (c) | ✔**1** |  |  |  |  |  |  |  |
| (d) | ✔**1** |  |  |  |  |  |  |  |
| (e) | ✔ |  |  |  |  |  |  |  |
| (f) | ✔**2** |  |  |  |  |  |  |  |
| (g) | ✔ |  |  |  |  |  |  |  |
| (h) | ✔ |  |  |  |  |  |  |  |
| (i) | ✔ |  |  |  |  |  |  |  |
| (j) | ✔ |  |  |  |  |  |  |  |
| (k) | ✔ |  |  |  |  |  |  |  |
| (l) |  | ✔ |  |  |  |  |  |  |
| (m) |  | ✔ |  |  |  |  |  |  |
| (n) |  |  |  | ✔ |  |  |  |  |
| (o) |  |  |  | ✔ |  |  |  |  |
| (p) |  |  | ✔ |  |  |  |  |  |
| (q) | ✔**1** |  |  |  |  |  |  |  |
| (r) |  |  |  |  |  |  | ✔ |  |
| (s) | ✔ |  |  |  |  |  |  |  |
| (t) | ✔**1** |  |  |  |  |  |  |  |
| (u) |  |  |  |  |  | ✔ |  |  |
| (v) | ✔ |  |  |  |  |  |  |  |
| (w) | ✔**3** |  |  |  |  |  |  |  |
| (x) | ✔**1** |  |  |  |  |  |  |  |
| (y) | ✔ |  |  |  |  |  |  |  |
| (z) | ✔ |  |  |  |  |  |  |  |
| (aa) |  |  |  |  |  | ✔ |  |  |
| (ab) |  |  |  |  |  |  |  | ✔ |

*1 where applicable | 2 Professional users | 3 Lay users*

# 

# Need support achieving MDR compliance in your labelling?

**Trinzo can support you in achieving MDR compliance in your labelling by:**

* Reviewing your existing labelling to identify what changes need to be made for MDR,
* Identifying the subsections of GSPR 23 that apply to your specific device(s),
* Identifying the ISO 15223-1 symbols that are applicable to your device(s),
* Remediating your existing IFU to meet the more stringent MDR requirements,
* Advising on the applicability of an IFU for your specific device(s) and generation of a suitable rationale where appropriate,
* Providing guidance on the UDI requirements for your device(s).
* 