

## Licence Agreement

### 1. LICENCE AGREEMENT

1.1. Once your registration to access the GMDN Database has been accepted by The GMDN Agency, access to the GMDN Database by you (the '**Licensee**' as defined below) is controlled by an electronic permit activated by entering a user ID and password. The user IDs and passwords are supplied by The GMDN Agency on a subscription basis. To be issued with such a user ID and password the Licensee must complete the Registration Form and submit it as directed.

1.2. By submitting the registration details required by The GMDN Agency in the Registration Form and by paying the relevant Licence Fee (where required) for accessing the GMDN Database, the Licensee agrees to be bound by the Terms and Conditions of this licence agreement and the relevant Schedule applicable to the type of licence as referred to in the Schedule as designated by The GMDN Agency in its absolute discretion. By submitting the Registration Form, the party identified as the Licensee is warranting that the information submitted is true and accurate and the person submitting the Registration Form is duly authorised on behalf of the Licensee to enter into this Agreement (as defined below). In exchange, The GMDN Agency will, subject always to the terms of this Agreement, grant the Licensee a licence to access the GMDN Database and for the Licensee to use the codes accessible from it on the following Terms and Conditions and relevant applicable Schedule.

### 2. TERMS AND CONDITIONS

#### 2.1. Definitions

2.1.1. In these Terms and Conditions, the terms defined in the Schedule shall have the meanings set out in the Schedule and the following terms shall have the following meanings, unless the context requires otherwise:

2.1.1.1. "**Agreement**" means these Terms and Conditions and the relevant Schedule;

2.1.1.2. "**Credit**" means a credit purchased from The GMDN Agency either as part of the Licence Fee (if relevant) or in addition to the Licence Fee, which credit can be redeemed against access to a single GMDN Code;

2.1.1.3. **"Collective Terms"** or **"Categories"** means collective terms for a particular group of GMDN Terms appearing on the GMDN Database;

2.1.1.4. **"Confidential Information"** means information in any form which is confidential in nature, including without limitation business information, personal data, financial information, information relating to the GMDN Database, and which is supplied or made available by the disclosing Party to the other Party as a result of, or in connection with, this Agreement, whether in writing, orally or otherwise;

2.1.1.5. **"Database Application Software"** means the Licensee's database application software as identified in the Schedule through which Users can access and search against the relevant GMDN Definitions, GMDN Codes, GMDN Terms and/or Collective Terms;

2.1.1.6. **"Data Protection Legislation"** means all applicable privacy and data protection laws, including without limitation the UK GDPR, the Data Protection Act 2018 (and regulations made thereunder), the Privacy and Electronic Communications Regulations 2003 (SI 2003/2426) and any applicable national implementing laws and regulations relating to the processing of personal data and the privacy of electronic communications, as amended, replaced or updated from time to time, including, to the extent the EU General Data Protection Regulation (Regulation 2016/679) applies, the law of the European Union or any member state of the European Union to which the GMDN Agency or the Licensee is subject relating to the protection of personal data (this may include the Privacy and Electronic Communications Directive (2002/58/EC) and the Privacy and Electronic Communications (EC Directive) Regulations 2003 (SI 2003/2426)).

UK GDPR has the meaning given to it in section 3(10) (as supplemented by section 205(4)) of the Data Protection Act 2018.

2.1.1.7. **"GMDN Definition"** means the specific definition for a medical device created by GMDN;

2.1.1.8. **"GMDN Code"** means the 5 digit nomenclature code used to identify a particular medical device as created by GMDN and available on the GMDN Database;

2.1.1.9. **"GMDN Database"** means the database comprising the list of internationally agreed descriptors used to identify medical device products available through the GMDN Website;

2.1.1.10. **"GMDN Term"** means the specific name given to a particular medical device as approved by GMDN;



2.1.1.11. **“Intellectual Property”** means patents, patentable rights, copyright, design rights, utility models, trade marks, trade names (including without limitation the Trade Marks), rights in inventions, rights in data, database rights, rights in know-how and confidential information and all other intellectual and industrial property and similar or analogous rights existing under the laws of any country (whether or not registered or registrable, whether present, future or contingent, and including without limitation all renewals, extensions, revivals and accrued rights of action) and all pending applications for and right to apply for or register the same;

2.1.1.12. **“Licence Fee”** means the licence fee identified in the relevant Schedule, which fee is dependent on the nature and size of the Licensee’s organisation and the type of licence required, in respect of which The GMDN Agency grants the Licensee access to the GMDN Database, and the relevant Credits identified in the Schedule;

2.1.1.13. **“Licensee”** means the party identified as the 'Licensee' in the Registration Form submitted to The GMDN Agency and falling into the Schedule specified by The GMDN Agency when it issues the relevant user ID and password;

2.1.1.14. **“Licensee Terms and Conditions”** means terms and conditions of use of the Database Application Software;

2.1.1.15. **“Party’ or ‘Parties”** means either The GMDN Agency or the Licensee or both as the context may require;

2.1.1.16. **“Purpose”** means the purpose for which the Licensee may use the GMDN Database as identified in the Schedule;

2.1.1.17. **“Registration Form”** means the electronic form complete

2.1.1.18. **“Term”** has the meaning given to it in Clause 9.1;

2.1.1.19. **“Trade Marks”** means GMDN;

2.1.1.20. **“The GMDN Agency Website”** means the GMDN website at [www.gmdnagency.org](http://www.gmdnagency.org); and

2.1.1.21. **“Users”** means, where relevant, users granted access through the Database Application Software to the relevant GMDN Definitions, GMDN Codes, GMDN Terms or Collective Terms in accordance with the terms of this Agreement.

2.2. Headings in the Agreement are inserted for convenience only and do not affect its interpretation.



2.3. Words importing the singular shall be deemed to include the plural and vice versa.

2.4. In the event of a conflict between these Terms and Conditions and the Schedule, the Schedule shall prevail.

### **3. GRANT OF RIGHTS**

3.1. In consideration of:

3.1.1. the payment of the relevant Licence Fee by the Licensee to The GMDN Agency; and

3.1.2. the acceptance of the obligations set out in this Agreement by the Licensee;

the GMDN Agency hereby grants to the Licensee for the Term a non-exclusive and non-transferable licence to access the GMDN Database from the GMDN Agency Website under the conditions specified in the Terms of Website Use and to use the GMDN Definitions, GMDN Codes, GMDN Terms or Collective Terms in accordance with the provisions of this Agreement. The right to access the GMDN Database will be in accordance with the Access Rights detailed in the Schedule.

3.2. The GMDN Database, GMDN Definitions, GMDN Codes, GMDN Terms and Collective Terms may only be used for the Purpose as defined in the Schedule.

3.3. The Licensee undertakes not to use or make accessible the GMDN Database in such a way that:

3.3.1. the GMDN Codes will be displayed on the Platform (other than as input by a User);

3.3.2. the GMDN Database, or the sets of GMDN Definitions, GMDN Codes, GMDN Terms or Collective Terms, will be accessible by Users or any third parties in its or their entirety, or substantially in its or their entirety.

3.4. The licence granted under clause 3.1 is issued in respect of the single site or address stated on the Registration Form and covers the access of the GMDN Database by Licensee personnel only and only on personal computers in use at that location. If the Licensee wishes to be granted a multi-site licence, this must be expressly selected. More information is available on request from The GMDN Agency.

3.5. Other than as expressly permitted in this Agreement, the Licensee undertakes not to use, access or allow any third party to access or use the GMDN Database other than as expressly permitted in this Agreement.



3.6. The Licensee shall not have any rights in or to the GMDN Database, the GMDN Codes, the GMDN Definitions, the Collective Terms or the GMDN Terms other than the rights specifically granted in this Agreement and all rights not expressly granted to the Licensee are reserved by The GMDN Agency and its licensors.

3.7. Subject to clause 7, nothing in this Agreement shall prevent The GMDN Agency from using or licensing others to use the GMDN Database.

#### **4. OBLIGATIONS OF THE LICENSEE**

4.1. The Licensee shall:

4.1.1. complete the Registration Form accurately;

4.1.2. at all times throughout the Term be responsible for how the GMDN Database is being used by its employees and consultants;

4.1.3. ensure that only authorised personnel shall have access to the Licensee ID and password provided by The GMDN Agency to enable the Licensee to access the GMDN Database and that such passwords and IDs are not disclosed to third parties. The Licensee agrees to indemnify The GMDN Agency from and against any loss, liability, damages or costs to The GMDN Agency or third parties from the Licensee's failure to comply with this obligation;

4.1.4. notify The GMDN Agency in writing immediately if the security of a password has been compromised, after which The GMDN Agency will issue a new password;

4.1.5. take all appropriate measures (in consultation with The GMDN Agency, where appropriate) to safeguard the Intellectual Property rights of The GMDN Agency in the GMDN Database; and

4.1.6. pay the relevant Licence Fees (as applicable) to The GMDN Agency as detailed in the Schedule;

4.1.7. ensure that the Licensee Terms and Conditions impose restrictions on the use which Users can make of the GMDN Definitions, GMDN Codes, GMDN Terms or Collective Terms which are no less strict than those imposed by The GMDN Agency on its licensed members as set out in the terms and conditions of use of the GMDN Database on The GMDN Agency Website;

4.1.8. procure that all users who use the GMDN Database comply with all relevant provisions of this Agreement and shall ensure that only Users who have signed up to Licensee Terms and Conditions shall be able to access GMDN Definitions, GMDN Codes, GMDN Terms and Collective Terms;



4.1.9. not use, copy, download, rent, lend, lease, sell, distribute, transmit or otherwise transfer any of the Database Application Software, data, GMDN Codes, GMDN Definitions, Collective Terms or GMDN Terms contained in the GMDN Database or any copy, modification, translation or adaptation of any such data, GMDN Codes, GMDN Definitions, Collective Terms or GMDN Terms except as permitted by law or expressly set out in this Agreement. The Licensee may not reverse compile, disassemble, reverse engineer or create derivative works based on all or any portion of the Database Application Software or GMDN Database; and

4.1.10. ensure that wherever the Licensee publishes or displays any GMDN Codes, GMDN Definitions, Collective Terms or GMDN Terms, the Licensee shall display with reasonable prominence a proprietary notice in accordance with the following wording:

‘GMDN’ is a registered trade mark of The GMDN Agency. All rights reserved. The copyright and database rights in the Database Application Software and original GMDN materials are owned by The GMDN Agency Ltd 2014–2016 (or as appropriate). Used under licence from The GMDN Agency Ltd.

4.1.11. promote the use of the GMDN nomenclature.

4.2. The Licensee shall not (other than as expressly permitted by The GMDN Agency):

4.2.1. process or incorporate the GMDN Database or any of the data, GMDN Codes, GMDN Definitions, Collective Terms or GMDN Terms contained in the GMDN Database into any Artificial Intelligence platform or application without the express prior written permission of The GMDN Agency (and for which a special licence will be required);

4.2.2. translate, adapt, vary, modify, disassemble, decompile or reverse engineer the Database Application Software or GMDN Database;

4.2.3. (and shall procure that no employee or agent of the Licensee shall) use, post, transmit, inject or introduce any file, device, software or routine that interferes or attempts to interfere with the Database Application Software or GMDN Database or any part of it, including, but not limited to, any virus, cancelbot, worm, denial of service routines, Trojan horse or any other contaminating or destructive feature.

4.3. In the event that the Licensee is approached by a third party in relation to using the GMDN Database in any format, the Licensee shall promptly refer the



third party to The GMDN Agency, except as permitted by law or expressly set out in this Agreement.

4.4. Where the Licensee submits an amendment, correction or addition to the GMDN Terms, GMDN Definitions or GMDN Codes (**'Licensee Submission'**), the Licensee acknowledges that the incorporation of such Licensee Submission into the GMDN Database is for the benefit of the Licensee as well as other licensees of The GMDN Agency. Accordingly, by submitting the Licensee Submission, the Licensee acknowledges that The GMDN Agency shall be entitled to review, amend and incorporate such Licensee Submission into the GMDN Database for use as the GMDN Agency sees fit during and after the Term.

4.5. The Licensee agrees that all rights in all Licensee Submissions will, to the fullest extent permitted by law, be owned by The GMDN Agency absolutely and that The GMDN Agency shall be entitled to use such amendments, additions or corrections as it wishes in its sole discretion and without any payment to the Licensee. The Licensee hereby assigns all rights in the Licensee Submissions to The GMDN Agency and agrees to execute all agreements required by The GMDN Agency at The GMDN Agency's cost to ensure such rights are vested in The GMDN Agency.

4.6. The GMDN Agency reserves the right to charge the Licensee an administrative charge for considering and amending a Licensee Submission (to ensure it is appropriate for inclusion in the GMDN Database) and incorporating such Licensee Submission into the Licensee Database.

4.7. The GMDN Agency reserves the right to publish the Licensee's name in its list of registered licensees and to refer to the fact that the Licensee is a registered licensee in the promotion of The GMDN Agency and the GMDN Database.

## **5. ACCESS TO THE GMDN DATABASE**

5.1. The GMDN Agency shall use all reasonable endeavours to provide reasonable access to the GMDN Database to the Licensee to allow it to exercise its rights under these Terms and Conditions.

5.2. The Licensee acknowledges that access to the GMDN Database may be occasionally restricted to allow for updates, repairs, maintenance or the introduction of new facilities or services. The GMDN Agency shall attempt to provide reasonable notice of any scheduled interruptions to such facility and shall seek to restore the GMDN Database as soon as reasonably possible.



5.3. The GMDN Agency retains the right to modify the Database Application Software and GMDN Database at any time, provided always that it shall give reasonable notice to the Licensee of any modifications which will materially affect the performance or functionality of the GMDN Database.

## **6. INTELLECTUAL PROPERTY RIGHTS**

6.1. All Intellectual Property rights in the Database Application Software, GMDN Database, the GMDN Codes, the Collective Terms, GMDN Terms and the GMDN Definitions are and shall remain vested in The GMDN Agency and its licensors, and save as specifically provided in this Agreement, no rights in the Database Application Software, GMDN Database or such data will pass to the Licensee under this Agreement.

6.2. The Licensee shall, subject to clause 4.1.1.10, be able to use the name 'GMDN' in relation to the Purpose and the Database Application Software, and shall be entitled to refer to itself as being an 'Authorised GMDN Licensee', provided always that the Licensee shall comply with all reasonable requirements of The GMDN Agency with regard to such use, and shall not be entitled to use The GMDN Agency's GMDN logo (in whatever format).

6.3. The Licensee shall promptly notify The GMDN Agency of any infringement, or suspected infringement, of any Intellectual Property in the Database Application Software or GMDN Database or any part of it which comes to the Licensee's notice.

## **7. PAYMENT**

7.1. Subject to the provisions of this Agreement, the Licensee shall pay all Licence Fees due, without deduction of any sort, to The GMDN Agency in accordance with the Schedule.

7.2. The Licensee shall punctually pay to The GMDN Agency all sums due to The GMDN Agency under this Agreement. In the event of any late payment The GMDN Agency shall be released from its obligations under this Agreement until the payment has been made.

7.3. The Licensee when paying for GMDN membership is responsible for all bank fees/charges when transferring money to the GMDN Agency from overseas.

## **8. WARRANTY, INDEMNITY, DISCLAIMER AND LIMITATION OF LIABILITY**

8.1. The GMDN Agency shall take all reasonable care to ensure that the GMDN Database is available and functioning at all times, but it does not guarantee





continuous, uninterrupted or secure access to the Database Application Software or GMDN Database, nor does it guarantee that the Database Application Software or GMDN Database is virus or error free. The Database Application Software and GMDN Database is accordingly provided "as is" and as and when available, and to the extent permissible by law The GMDN Agency and its licensors hereby exclude all implied warranties, conditions or other terms, whether implied by statute or otherwise in relation to the Database Application Software and GMDN Database.

8.2. The GMDN Agency warrants that the English language version of the GMDN Terms and GMDN Definitions are correct but makes no warranties and The GMDN Agency and its licensors accept no liability as regards translated versions.

8.3. The GMDN Terms and GMDN Definitions are used to provide conformed descriptions of Categories of medical devices to which a medical device belongs, and none of the GMDN Terms, GMDN Definitions or GMDN Database constitutes any endorsement, advice, representation or warranty about any specific medical devices that may be described by such terms or definitions. In particular, no representation or warranty is made in relation to: instructions for use; suitability for any application, treatment or condition; regulatory status; or any properties of a particular medical device. For any such information the Licensee and any Users should refer to the relevant manufacturer. Medical devices must always be used in accordance with the manufacturer's instructions for use.

8.4. The Parties warrant that they will comply with their relevant obligations under this Agreement.

8.5. The Licensee warrants that all information submitted to The GMDN Agency in the Registration Form is correct and that the person signing the Registration Form is duly authorised on behalf of the Licensee.

8.6. Subject to clauses 8.7, 8.8 and 8.9, the Licensee hereby indemnifies and will hold The GMDN Agency harmless from and against any losses incurred by or damages, account of profits and/or costs awarded against it in any action or (after and in accordance with the advice of Counsel paid by the other party to settle any claim) arising as a consequence of the breach by the Licensee of any of its warranties given in this Agreement.

8.7. Nothing in this Agreement will operate to limit or exclude either party's liability for death or personal injury resulting from negligence, fraud; or any liability which cannot be excluded by applicable law.



8.8. Subject to clause 8.9, the maximum liability of The GMDN Agency under or in connection with this Agreement in relation to any single event or series of connected events will be the Licence Fees paid by the Licensee to The GMDN Agency in the 12-month licence period during the Term in which the claim arose.

8.9. Subject to clause 8.7, The GMDN Agency will not be liable to the Licensee for any of the following:

8.9.1. loss of revenue, loss of actual or anticipated profits whether arising in the normal course of business or otherwise (including, without limitation, loss of profits on contracts); loss of the use of money; loss of anticipated savings; loss of business; loss of opportunity; loss of goodwill; loss of or damage to reputation; loss of or corruption to data; loss of management or administration time, legal and other professional fees and expenses; or

8.9.2. any indirect or consequential loss or damages however caused which arise directly or indirectly from the subject matter of this Agreement.

8.10. The Licence Fees charged by The GMDN Agency under this Agreement are calculated with specific reference to the level of liabilities assumed by it and, accordingly, the Licensee agrees that the limitations and exclusions of liability in this Agreement are reasonable.

## **9. TERM AND TERMINATION**

9.1. Unless The GMDN Agency terminates it in accordance with clause 9.2 below, this Agreement will begin on the date on which The GMDN Agency issues the Licensee with a user ID and password to access the GMDN Database and will continue for a year (the '**Term**'), after which the Licensee will need to renew this Agreement by confirming renewal and paying, where relevant, a further Licence Fee corresponding to the relevant licence granted for the following year. The GMDN Agency will send an electronic message each month to each user that subscribes to the Newsletter to remind them of their renewal date. If the Licensee does not renew its subscription, the account will no longer be active and the Licensee's rights under this Licence automatically cease and the Licensee will no longer have access to the Database Application Software or GMDN Database.

9.2. Without prejudice to any other right or remedy it may have, either Party will have the right to terminate this Agreement immediately at any time by notice to the other if the other Party ('the **Defaulting Party**):



9.2.1. breaches and/or fails to perform any material provision of this Agreement, and either such failure is incapable of remedy; or such failure is capable of remedy and has not been remedied by the Defaulting Party within 14 days of notice in writing specifying the failure and requiring it to be remedied being given by the Party not in breach;

9.2.2. is unable to pay its debts as they fall due or is otherwise insolvent; or has a receiver appointed to manage its business or assets; or is the subject of any steps to wind it up for any reason other than the reorganisation of the group of companies to which it belongs (if applicable); or any event occurs in any jurisdiction to which the Defaulting Party is subject which has an effect equivalent or similar to any events mentioned in this clause 9.2.2.

9.3. The GMDN Agency will have the right to terminate this Agreement immediately at any time by notice to the Licensee if at any time control (meaning the ability to direct the affairs of the other Party, whether by virtue of the ownership of shares or by contract) is acquired by any entity not having control of the Licensee at the date this Agreement starts.

9.4. On termination or expiry of this Agreement for any reason:

9.4.1. the provisions of Clauses 4.1.7, 6, 8.6, 9.4, 10, and 11 will continue in force;

9.4.2. the Licensee shall immediately cease all further use of the GMDN Database;

9.4.3. The GMDN Agency shall not be obliged to pay any refund for any portion of any Licence Fees paid by the Licensee relating to any remaining part of the relevant year after termination; and

9.4.4. all rights and obligations of the parties (other than any accrued rights of action and liabilities or obligations which expressly or by implication are to come into or continue in force on or after termination of this Agreement) shall automatically cease and terminate.

## **10. CONFIDENTIALITY**

10.1. Neither Party will use, copy, adapt, alter, transmit, broadcast, make available, disclose or part with possession of Confidential Information, whether marked confidential or not, except as strictly necessary to perform its obligations or exercise its rights under this Agreement, provided that this obligation will not apply to Information which the receiving Party can prove was in its possession at the date it was received; or the receiving Party can prove has been obtained from a third Party with good legal title; or comes into the public domain other than through the default or negligence of the receiving Party; or the receiving Party can



prove is independently developed by or for the receiving Party; or is required to be disclosed by an order of any court of competent jurisdiction or governmental authority, or by the requirements of any stock exchange on which the shares of the receiving Party are listed or are to be listed (provided that the receiving Party will take all reasonable steps to minimise the scope of the disclosure).

## **11. DATA PROTECTION**

11.1. Capitalised terms used and not defined in this Agreement shall bear the meanings given to them in the Data Protection Legislation.

11.2. Both parties will comply with all applicable requirements of the Data Protection Legislation. This clause 11 is in addition to, and does not relieve, remove or replace, a party's obligations or rights under the Data Protection Legislation.

11.3. The GMDN Agency may collect certain information about the Licensee and its personnel, representatives and agents, in connection with this agreement, as set out in the then-current version of The GMDN Agency's privacy policy, available here. In the event of any inconsistency or conflict between the terms of the then-current privacy policy and this Agreement, the privacy policy will take precedence.

11.4. The parties acknowledge that for the purposes of this Agreement, Personal Data is processed by The GMDN Agency as a Controller for the purposes of the Data Protection Legislation.

11.5. Without prejudice to the generality of clause 11.1 the Licensee will ensure that it has all necessary appropriate consents and notices in place to enable lawful transfer of any personal data to The GMDN Agency for the duration and purposes of this agreement.

11.6. In the event the transfer of any Personal Data between the Parties will result in Personal Data leaving the United Kingdom or European Economic Area the Controller to Controller (Module 1) Standard Contractual Clauses (annexed to European Commission decision (EU) 2021/914 2021) ("EU SCCs") together with the UK International Transfer Addendum to the EU SCCs ("UK Addendum"), shall apply and are incorporated into this Agreement as if they had been set out in full.

11.7. Incorporation of the international data transfer provisions:

### **Part A: The EU SCCs**

The Parties

**Data Importer name** the Licensee



**Data Importer address** as set out on the Registration Form by the Licensee

**Data Importer telephone** as set out on the Registration Form by the Licensee

**Data Importer email** as set out on the Registration Form by the Licensee

**Data Exporter name** The GMDN Agency

**Data Exporter address** Hampden House Monument Park, Chalgrove, Oxford, Oxfordshire, England, OX44 7RW

**Data Exporter telephone** +44 (0) 1235 799759

**Data Exporter email** [Contact Us](#)

#### Description of Data Processing

**Categories of Data Subjects** the Licensee, the Licensee's employees and consultants

**Purpose and nature of the transfer(s)** in order to fulfil its obligations under this Agreement and to provide the Licensee with access to the GMDN Database as set out in this Agreement.

**Categories of personal data transferred** names, addresses, email addresses and date of birth.

**Recipients** The GMDN Agency, its employees, consultants and affiliates.

**Special categories of data** N/A

**Frequency of the transfer** continuous.

**Competent supervisory authority** The Irish Data Protection Commissioner.

**Data protection registration information of the data exporter** as discussed between the parties.

**Contact points for data protection enquiries** as set out in the Registration Form.

#### **Clarifications to the Standard Contractual Clauses**

For the purposes of clause 8.2 of the EU SCCs and to enable data subjects to effectively exercise their rights, the parties have agreed that the exporter shall inform data subjects of the information required.

For the purposes of clause 8.3 of the EU SCCs the parties hereby agree that the exporter shall be primarily responsible for ensuring that Personal Data is accurate and, where necessary, kept up to date. The exporter shall take every reasonable



step to ensure that Personal Data that is inaccurate, having regard to the purpose(s) of processing, is erased or rectified without delay.

For the purposes of clause 13 of the EU SCCs, the competent Supervisory Authority shall be The Irish Data Protection Commissioner.

For the purposes of clauses 17 and 18 of the EU SCCs, the parties agree that the governing law and choice of jurisdiction shall be where the exporter is established. If those laws do not allow for third party rights, the law of Ireland shall apply, and the courts of Ireland will have exclusive jurisdiction.

## **Part B: The UK Addendum**

### Parties

As set out in Part A

### Selected SCCs, Modules and Clauses

Module 1 of the EU SCCs and no other optional clauses unless explicitly specified, and as amended by the clarifications in Part A, but subject to any further amendments detailed in this Part B.

### Appendix Information

The processing details required by the UK Addendum are as set out in Part A.

### Termination of the UK Addendum

In the event the template UK Addendum issued by the Information Commissioner's Office and laid before Parliament in accordance with s119A of the DPA 2018 on 2 February 2022, as it is revised under Section 18 is amended, either party may terminate this Part B on written notice to the other in accordance with Table 4 and paragraph 19 of the UK Addendum and replace it with a mutually acceptable alternative.

The GMDN Agency reserves the right to amend and update the information set out in clause 11.7 at any point during the Term at its sole discretion.

## **12. GENERAL**

12.1. The Licensee shall not transfer, assign, sub-license or otherwise dispose of all or any part of this Agreement, or any of its rights or obligations arising under it without the prior written consent of The GMDN Agency.

12.2. If any provision of this Agreement is declared void or unenforceable the remaining provisions of this Agreement shall remain in full force and effect.



12.3. Nothing in this Agreement shall be deemed to constitute a partnership between the Parties or constitute any Party the agent of the other Party.

12.4. Nothing in this Agreement is intended to confer any benefit on any third party (whether such benefit would have arisen under the Contracts (Rights of Third Parties) Act 1999 or otherwise) and no term will be enforceable by any third party.

12.5. No amendment or variation to this Agreement shall take effect unless it is in writing, signed by authorised representatives of each of the Parties.

12.6. This Agreement and the Registration Form constitute the entire agreement between the Licensee and The GMDN Agency and supersedes any previous arrangement, understanding or agreement between the Licensee and The GMDN Agency relating to the GMDN Database.

12.7. This Agreement shall be governed by and construed in accordance with the laws of England and Wales and the Courts of England and Wales shall have exclusive jurisdiction.

Updated: 9 September 2024

## **SCHEDULE A – for a GOVERNMENT DEPARTMENT**

**1 Definition.** For the purposes of this Agreement a 'Government Department' is an organization recognized by a national government as being the body responsible for the regulation or approval of medical devices and other Government Departments in the same country connected with the Licensee can be considered to be part of the Licensee.

**2 Purpose.** Use of the GMDN nomenclature for regulatory purposes where there is a need for general descriptors for identification purposes. The Licensee is further permitted to integrate the GMDN Database into its intranet IT domain for internal access only. The Licensee shall not be entitled to release or provide access to any part of the GMDN Database to any other party, except for specific regulatory investigations when access to individual GMDN Terms may be necessary.

Where the Licensee wishes to grant limited public access, the Licensee needs to seek specific consent from The GMDN Agency. The GMDN Agency may in such circumstances grant an extension to this Licensee to allow the Licensee to allow public access to single GMDN term, but not GMDN Codes. In such circumstances the public will not be entitled to store or save such information.



**3 Access Rights.** The Licensee shall have access to all GMDN Terms, GMDN Definitions and GMDN Codes.

#### **SCHEDULE B – for a PUBLIC HEALTHCARE PROVIDER**

**1 Definition.** For the purposes of this Agreement a 'Public Healthcare Provider' is an organization concerned with the purchase, control and utilization of medical devices for purposes of administering public healthcare to patients. For example, a hospital or clinic.

**2 Purpose.** Use of the GMDN nomenclature for the purpose of inventory, purchasing and e-commerce purposes, medical device maintenance and other technical uses.

**3 Access Rights.** The Licensee shall have access to all GMDN Terms, GMDN Definitions and GMDN Codes.

#### **SCHEDULE C – for a CONFORMITY ASSESSMENT BODY**

**1 Definition.** For the purposes of this Agreement a 'Conformity Assessment Body' is an organization recognized by a national government for the purpose of medical device testing, certification or approval. For example, a European Notified Body or Government Inspector.

**2 Purpose.** Use of the GMDN nomenclature for regulatory purposes where there is a need for general descriptors for identification purposes.

The Licensee is permitted to integrate the GMDN into its intranet IT domain for internal access only.

The Licensee may grant access to the GMDN Database for all entities governed by the Licensee body within its regulatory environment. However, the Licensee shall not be entitled to release or provide access to any part of the GMDN Database to any other party, except for specific regulatory investigations when access to individual GMDN Terms may be necessary.

**3 Access Rights.** The Licensee shall have access to all GMDN Terms, GMDN Definitions and GMDN Codes.

#### **SCHEDULE D – for an ACADEMIC RESEARCHER**

**1 Definition.** For the purposes of this Agreement an 'Academic Researcher' is a person or organization concerned with the study or research related to medical devices and their use. It does not include study or research that has a





commercial outcome in respect to a medical device. In this case refer to Schedule B for Manufacturers.

**2 Purpose.** Use of the GMDN nomenclature for the purpose of research and academic study by the Licensee, provided always that The GMDN Agency has approved the proposed scope of the relevant study in advance after submission by the Licensee (along with such evidence of the researcher's relationship with the relevant academic institution as reasonably required by The GMDN Agency where the Licensee is an individual) to The GMDN Agency of the relevant study outline (such approval not to be unreasonably withheld). This does not confer the right to publish GMDN Codes, GMDN Terms or GMDN Definitions in any journal, website or scientific paper without specific written consent from The GMDN Agency.

**3 Access Rights.** The Licensee shall be entitled to access the GMDN Database solely for the Purpose and shall be issued with the relevant number of Code Credits when joining for the first time.

#### **SCHEDULE E – for a BASIC USER**

**1 Definition.** For the purposes of this Agreement a 'Basic User' is any natural or legal person required by regulation to use the GMDN.

**2 Purpose.** Use of the GMDN nomenclature for the Licensee's internal purposes to code its medical products. A Licensee may provide the GMDN Code to their customer or regulator in relation to their specific products.

**3 Access Rights.** The Licensee shall be entitled to access the GMDN Database and shall be issued with the relevant number of Code Credits when joining for the first time.

#### **SCHEDULE F – for a MANUFACTURER**

**1 Definition.** For the purposes of this Agreement a 'Manufacturer' is an organization that manufactures or supplies medical devices or their representative. For example, this would include a Labeller, an Agent, a Sponsor, a Distributor or a Wholesaler.

**2 Purpose.** Use of the GMDN nomenclature solely for the Licensee's internal business purposes to code its medical products. A Licensee may provide the GMDN Code to their customer or regulator in relation to their specific products.



**3 Access Rights.** The Licensee shall be entitled to access the GMDN Database and shall be issued with the relevant number of Code Credits when joining for the first time.

## **SCHEDULE G – for a CONSULTANCY ORGANISATION AND OTHER COMMERCIAL ORGANISATIONS**

**1 Definition.** For the purposes of this Agreement a 'Consultancy Organisation and Other Commercial Organisations' means organisations concerned with providing consulting services and products to manufacturers of medical devices or their representatives, or to other stakeholders for profit.

**2 Purpose.** Use of the GMDN nomenclature solely for the Licensee's internal business purposes to code its medical products, provided always that the proposed use of the GMDN Database is subject to the prior written approval of The GMDN Agency and will not, in the reasonable opinion of The GMDN Agency, compete with the business of The GMDN Agency. A Licensee may provide the GMDN Code to their customer / regulator in relation to their specific products.

**3 Access Rights.** The Licensee shall be entitled to access the GMDN Database and shall be issued with the relevant number of Code Credits when joining for the first time.

