# Agreement for WMDA Certification / Qualification / Accreditation

# Agreement number ION/WACC

# The undersigned:

The association established under the laws of the Netherlands **World Marrow Donor Association**, having its registered office at Schipholweg 57, 1st floor, unit 2, 2316 ZL Leiden, The Netherlands, registered at the Dutch Chamber of Commerce with number 40448326, duly represented in this matter by Ms L.M. Foeken-van Goozen, executive director; (hereinafter: “WMDA” or “Certification Body”)

and

{**NAME of applicant organisation**},, having its registered office at {address, including country}, duly represented in this matter by {NAME of representative} (hereinafter: “Registry”)

WMDA and Registry will be jointly referred to hereinafter as the "Parties";

**Whereas:**

* WMDA’s mission is to promote global collaboration and the sharing of best practices for the benefit of hematopoietic stem cell donors and transplant patients.
* Registry is an organisation responsible for the coordination of the search for hematopoietic stem cells from donors (including cord blood) unrelated to the potential patient and for providing hematopoietic stem cell products from volunteer donors to patients in need of a transplant.
* WMDA has set forth the minimum guidelines to facilitate hematopoietic stem cell transplantation and cell therapies. The WMDA Standards include processing of incoming requests, facilitating outgoing requests and coordinating the activities of donor, collection, and transplant centres, and cord blood banks. (hereinafter: “WMDA Standards”). The WMDA Standards are published on WMDA’s website (<https://wmda.info/professionals/quality-and-accreditation/wmda-standards/>).
* WMDA is the holder of the rights to an assessment program that enables Registry to become WMDA certified, qualified and/or accredited (hereinafter: “WMDA Certification Scheme”). The WMDA Certification Scheme is an opportunity for organisations to show that they are committed to following WMDA Standards. The final goal of the WMDA Certification Scheme is to provide the best qualified ‘product’ for the patient while protecting the health and well-being of donors.
* Registry wishes to become WMDA certified, qualified and/or accredited and has filed a letter of intent to that effect dated [Date Letter of Intent] (hereinafter: “Letter of Intent”).
* The Parties wish to lay down the arrangements they have made in this respect in this agreement (hereinafter: “Certification Agreement”).

**In consideration of the above, the Parties agreed on the following:**

### Certification, qualification and accreditation

* 1. There are three levels to the WMDA Certification Scheme: certification, qualification and accreditation. Registries must meet a minimum volunteer donor/cord blood unit registry size and must have a specific activity level in order to apply for qualification or accreditation. Qualification is granted for the initial application and accreditation is granted for the second and subsequent applications. Certification is designed for registries that have insufficient activity levels and can be renewed. The requirements are described in policies that are publicly available on the WMDA membership website (hereinafter: “WMDA Share”) and available on request at accreditation@wmda.info .
	2. Registry will indicate the level of certification it seeks to obtain in Letter of Intent, available on WMDA website (https://wmda.info/professionals/quality-and-accreditation/wmda-accreditation-programme/).
1. **WMDA Standards**
	1. WMDA Standards are developed by the Standards Committee and approved by the WMDA Board based on recommendations of the WMDA membership. The most recent version of the WMDA Standards is publicly accessible on WMDA's website (<https://wmda.info/professionals/quality-and-accreditation/wmda-standards/>). Changes to and/or new WMDA Standards are based on membership consultation followed by a public consultation. The new version of WMDA Standards is posted on the WMDA website prior to implementation. The transition period is defined as six months, unless the WMDA Board decides that changes of the WMDA Standards need to be implemented sooner.
	2. For certification or qualification, Registry shall comply with the 'benchmark' WMDA Standards. These standards are clearly labelled in the WMDA Standards.
	3. For accreditation, Registry shall comply with all WMDA Standards.
2. **Assessment to determine compliance with the WMDA Standards**
	1. WMDA will assess whether Registry complies with the WMDA Standards according to the WMDA Certification Policies, available on WMDA Share. WMDA may update the WMDA Certification Policies from time to time.
	2. For accreditation, Registry will also be evaluated by an on-site or remote audit.
	3. The application is either approved or disapproved by the Accreditation Committee. If approved, the Registry will receive a certificate noting the level achieved (certification/qualification/accreditation) and the approved stem cell source (volunteer donors and/or cord blood).
	4. The second year during the 4-year cycle of certification/qualification/accreditation, Registry shall submit a mid-cycle surveillance to WMDA. This mid-cycle surveillance is evaluated by a reviewer and their assessment will be reviewed by the Accreditation Committee. The registry’s progress will either be deemed satisfactory or unsatisfactory. The Registry will receive the conclusion of the mid-cycle surveillance in a written report.
3. **WMDA responsibilities**
	1. WMDA will identify competent reviewers who have been trained through the WMDA Reviewers’ Training Program.
	2. WMDA will assign reviewers to an application, but Registry will be given an opportunity to request different reviewers if a conflict of interest exists through the Letter of Intent. A list of reviewers is available on request at accreditation@wmda.info.
	3. WMDA will, to the best of its abilities, complete the review in a timely fashion and provide Registry with a written report and the decision regarding its application.
	4. WMDA will perform the WMDA Certification Scheme assuming local laws, rules and regulations do not provide obligatory limitations or specific requirements for this type of activity. Parties agree that it is the responsibility of Registry to investigate and inform WMDA of any obligatory limitation or requirement under legislation applicable to the WMDA Certification Scheme. Unless WMDA was informed up-front of the specific limitation or requirement causing damages, Registry shall indemnify and hold WMDA harmless for damages that are attributable to non-compliance with such legislation.
4. **Registry responsibilities**
	1. Registry will continuously comply with the latest active version of the WMDA Standards and address any deficiencies identified during any evaluation process.
	2. Registry will prepare a standard operating procedure to facilitate the preparation of subsequent documentation demonstrating compliance with WMDA Standards (e.g., during the assembly of the next application).
	3. Registry will review an application training video three months prior to submission.
	4. Registry makes all necessary arrangements for the conduct of the evaluations, including, if applicable:
* provision for examining documentation and records, and access to the relevant equipment, location(s), area(s), personnel and Registry’s subcontractors to demonstrate compliance with WMDA Standards. Entities serving the Registry off-site (e.g. donor centres, collection centres) will be evaluated based on documentation held at the Registry and/or audits performed by the Registry itself.
* provision of all the necessary documentation and records to demonstrate compliance with WMDA Standards through a mid-cycle surveillance.
* the participation of personnel from the Accreditation Committee or personnel of the Certification Body to attend as an observer during on-site audits conducted by WMDA.
	1. Registry will not make misleading or unauthorized claims about (the scope of) its certification / qualification / accreditation status.
	2. Registry will not use its certification / qualification / accreditation status to bring the WMDA into disrepute.
	3. Registry will alert WMDA, without delay, of any changes that may affect its ability to conform with the certification requirements.
	4. Registry represents and warrants that it is in compliance with local laws, rules and regulations that may relate to the WMDA Standards.
	5. Registry will identify a staff member with the appropriate credentials and experience to serve as a WMDA reviewer unless excused by the Accreditation Steering Committee.
1. **Publicity and confidentiality**
	1. The Registry may use the WMDA logo on its documents and its web site. It will utilize the WMDA logo under the conditions listed in “Instruction for WMDA Logos and Trademarks” found in WMDA Share and shall discontinue its use upon suspension or termination of certification, qualification and/or accreditation.
	2. If Registry provides copies of a certificate to others, the certificate shall be reproduced in its entirety.
	3. WMDA will list the status of the Registry on its WMDA Share site and linked to donors provided by the Registry in Search & Match Service of WMDA.
	4. All evaluators of an application shall sign a confidentiality agreement and are required to avoid any conflicts of interest. Reviewers, members of Accreditation (Steering) Committee and WMDA personnel involved in the WMDA Certification Scheme will acquire and have access to information regarding the practices and procedures of registries seeking or maintaining certification, qualification or accreditation. This information is confidential and will not be disclosed or made available to any person, organisation, association, or other entity, unless obliged by law or with Registry’s approval.
	5. Except as needed to perform the assessment process, WMDA shall not reveal the status of a Registry’s application until approved to third parties without the express permission of Registry.
2. **Data protection**
	1. The Parties agree that all personal data processed in the performance of this Certification Agreement will be protected in accordance with the Data Use Agreement in place between the parties. The Data Use Agreement defines the bilateral, detailed expectations for the security and privacy of personal information between parties that applies to all aspects to the service, including acts necessary to perform registry accreditation and other means necessary to govern registry operations. The following data protection clauses provide additional requirements beyond those specified in the Data Use Agreement:
	2. The sending of data is obligatory. The Registry only submits records without fully identifiable data of either a donor or a recipient in the application. For curriculum vitae (CV) the WMDA template is used.
	3. The parties acknowledge that all recorded data shall be kept in archives and databases and treated as part of the management of all actions related to the present agreement.
	4. WMDA will maintain data acquired throughout and relevant to the application and renewal process for 2 completed application cycles with a minimum of 8 years based on its document retention policy and/or as long as legal obligations apply. Applicants will receive a notification of deletion of provided data / information.
	5. The WMDA processes data in order to fulfil its duties as conferred under the WMDA Certification Scheme. This can mean that WMDA shares data as defined in 7.2, with reviewers or other representatives of certification body as required to make a decision with regard to certification/qualification/accreditation or bodies that are auditing the WMDA certification body.
3. **Suspension, complaints and dispute resolutions**
	1. WMDA may terminate or suspend certification, qualification, or accreditation based on the findings from evaluations obtained during the period of certification, qualification or accreditation or based on findings arising from a complaint. The policies and procedures for investigation of complaints and suspension/termination are described in WMDA Share.
	2. Registry may request that a decision to disapprove WMDA certification / qualification / accreditation be appealed by submitting a written request to the WMDA office within three (3) months of receiving notification of the WMDA decision. This request shall include a justification why the decision should be reversed. The process for appeals, complaints and dispute resolution is described in WMDA Share.
	3. The Registry will keep a record of all complaints made known to it relating to compliance with certification requirements, take appropriate action to address the complaints and document the actions taken. Records of these complaints shall be available to the WMDA on request, including to reviewers during any audit.
4. **Fees**
	1. An initial fee is charged upon filing a Letter of Intent to apply for WMDA certification, qualification. Registry owes this fee to WMDA at the time the application is submitted to WMDA. This fee can be found in the WMDA price list on WMDA Share.
	2. The Registry does not pay for reviewer travel and lodging during on-site inspections required for accreditation.
	3. After submitting a first application for certification / qualification / accreditation, an annual fee will be charged (ongoing fee). The fee is billed in January of each year on the annual WMDA invoice.
	4. All fees applicable to the WMDA Certification Scheme are described publicly on the WMDA web site. WMDA may change these fees by giving 1 month’s notice.
5. **Governing law and jurisdiction**
	1. The Certification Agreement is governed by the laws of the Netherlands. Any dispute related to this Certification Agreement, whether in contract, tort, or otherwise, shall be brought exclusively before the courts of The Hague in the Netherlands.
6. **Liability, warranty disclaimer, indemnity**
	1. A grant of certification / qualification / accreditation by WMDA is recognition of Registry’s performance at the time of assessment by WMDA; certification / qualification / accreditation does not constitute a warranty of complete or continuous compliance with the Certification Scheme.
	2. WMDA shall not in any circumstances have any liability for any losses or damages which may be suffered by Registry as a result of the WMDA Certification Scheme.
	3. Registry shall indemnify and hold harmless WMDA, its employees, WMDA reviewers and members of the WMDA Accreditation Committee against all claims, demands, actions or proceedings made or brought (whether successfully or otherwise) by or on behalf of any individual, or private or public legal entity, in connection with damages, including financial consequences of personal injury or death, arising out of any Registry activity performed at the sites that are or were part of a certification, qualification or accreditation process under this Certification Agreement.
	4. The limitation of liability, disclaimer of warranty and indemnity shall survive the termination of this Certification Agreement.
7. **Duration and termination of Certification Agreement**
	1. This Certification Agreement will enter into force on the date of signature by the final (second) party to sign the Certification Agreement and will be valid until terminated by WMDA or the Registry.
	2. WMDA is entitled to terminate this Certification Agreement with immediate effect by giving written notice to the Registry if the Registry does not or not fully perform one or more of its obligations arising from the WMDA Certification Scheme or this Certification Agreement.
	3. The Registry is entitled to terminate this Certification Agreement with immediate effect by giving written notice to WMDA.

## Thus, agreed and signed electronically

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Authorised Representative of Registry

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name Authorised Representative of Registry

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Authorized Representative of WMDA

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Printed Name Authorised Representative of WMDA