	WMDA Certification Agreement			
	Document type	Agreement	Approved by	CEO WMDA
	Document reference	ACC-4120-F	Approval date	11/29/2024
	Version	5	Approval status	approved
	Pillar / Scope	P4/ Certification body	Status	Confidential

Agreement for WMDA Benchmark L1/Benchmark L2/Full Standards Certification

Agreement number ION/WACC

The undersigned:

The association established under the laws of the Netherlands, **World Marrow Donor Association (WMDA)**, having its registered office at Schipholweg 57, 1st floor, unit 19, 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, Chief Executive Officer; (hereinafter: “WMDA” or “Certification Body”)

and

{**NAME of applicant organisation**}, assigned the ION {**ION**}, 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 work with our members to ensure reliable provision of life-saving cells while promoting care and safety for both patient and donor.
- Registry is an organisation responsible for the coordination of the search for haematopoietic stem cells from donors (including cord blood) unrelated to the potential recipient and for providing haematopoietic stem cell products from volunteer donors to patients in need of a transplant.
- WMDA has set forth the minimum guidelines to facilitate haematopoietic stem cell transplantation and cell therapies. The WMDA International Standards for Unrelated Haematopoietic Stem Cell Donor Registries (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 ([Ensuring Quality | WMDA](#)).

WMDA is the holder of the rights to an assessment program that enables Registry to become WMDA Benchmark L1 or L2 and/or Full Standards certified (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 has filed a letter of intent to that effect dated [**Date Letter of Intent**] (hereinafter: “Letter of Intent”).

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- 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:

1. Benchmark L1/Benchmark L2/Full Standards compliance status

- 1.1. There are three levels to the WMDA Certification Scheme: Benchmark L1 / Benchmark L2 / Full Standards status. Registry must meet a minimum volunteer donor/cord blood unit registry size. Registry must have a specific activity level to apply for Benchmark L2 or Full Standards Certification status. Benchmark L2 is granted for the initial application and Full Standards is granted for the second and subsequent applications. Benchmark L1 is designed for registries that have insufficient activity levels and can be renewed. The requirements are described in policies that are available on the WMDA membership website (hereinafter: “WMDA Share”) and available on request at accreditation@wmda.info.
- 1.2. Registry will indicate the level of certification it seeks to obtain in the Letter of Intent, available on WMDA’s website ([Ensuring Quality | WMDA](#)).

2. WMDA Standards

- 2.1. WMDA Standards are developed by the Standards Committee and approved by the WMDA Membership Board based on recommendations of the WMDA membership. The most recent version of the WMDA Standards is publicly accessible on WMDA's website ([Ensuring Quality | WMDA](#)). 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’s website prior to implementation. The transition period is defined as six months, unless the WMDA Membership Board decides that changes of the WMDA Standards need to be implemented sooner.
- 2.2. For Benchmark L1 or Benchmark L2 Certification, Registry shall comply with the 'benchmark' WMDA Standards. These standards are clearly labelled in the WMDA Standards.
- 2.3. For Full Standards Certification, Registry shall comply with all required WMDA Standards.


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3. Assessment to determine compliance with the WMDA Standards

- 3.1. 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.
- 3.2. For Full Standards Certification, Registry will also be evaluated by an on-site or remote (video conference) audit.
- 3.3. The application is either approved or disapproved by the WMDA Certification Committee. If approved, Registry, **assigned the ION {ION}**, will receive a certificate noting the level achieved (Benchmark L1 / Benchmark L2 / Full Standards) and one or more of the services that have been certified. Certified services include: (1) receive requests for searches; maintain a searchable database; (2) coordinate the provision of adult volunteer donors as a source of stem cells; (3) coordinate the provision of umbilical cord blood units as source of stem cells; and/or (4) provide support for search requests from the registry’s transplant centres.
- 3.4. The second year during the 4-year cycle of Benchmark L1 / Benchmark L2 / Full Standards certification, 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 WMDA Certification Committee. Registry’s progress will either be deemed satisfactory or unsatisfactory. Registry will receive the conclusion of the mid-cycle surveillance in a written report.


4. WMDA responsibilities

- 4.1. WMDA will identify competent evaluators who have been trained through the WMDA Reviewers’ Training Program.
- 4.2. Registry will be given an opportunity to provide a list of evaluators with a potential conflict of interest through the Letter of Intent. A list of evaluators is available on WMDA Share (<https://share.wmda.info/x/So1JAQ>).
- 4.3. 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.

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5. Registry responsibilities

- 5.1 Registry will continuously comply with the latest active version of the WMDA Standards and address any deficiencies identified during any evaluation process.
- 5.2 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).
- 5.3 Registry will review application training materials available through the [WMDA Educational platform](#) three months prior to submission of the application.
- 5.4 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, transplant centres, cord blood banks) will be evaluated based on documentation held at the Registry and/or audits performed by 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 Certification Body to attend as an observer during on-site audits conducted by WMDA.
- 5.5 Registry will not make misleading or unauthorized claims about (the scope of) its Benchmark L1 / Benchmark L2 / Full Standards Certification.
- 5.6 Registry will not use its Benchmark L1 / Benchmark L2 / Full Standards Certification to bring the WMDA into disrepute.
- 5.7 Registry will alert WMDA, without delay, of any changes that may affect its ability to conform with the certification requirements.
- 5.8 Registry represents and warrants that it is in compliance with local laws, rules and regulations that may relate to the WMDA Standards.
- 5.9 Registry will identify a staff member with the appropriate credentials and experience to serve as a WMDA reviewer unless excused by the Certification Steering Committee.


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6. Publicity and confidentiality

- 6.1. 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 Benchmark L1 / Benchmark L2 / Full Standards Certification.
- 6.2. If Registry provides copies of its certificate to others, the certificate shall be reproduced in its entirety.
- 6.3. WMDA will list the status of Registry on its WMDA Share site and linked to donors provided by Registry in Search & Match Service of WMDA.
- 6.4. All evaluators of an application shall sign a confidentiality agreement and are required to avoid any conflicts of interest. Evaluators, members of Certification (Steering) Committee and WMDA personnel involved in the WMDA Certification Body will acquire and have access to information regarding the practices and procedures of registries seeking or maintaining Benchmark L1 / Benchmark L2 / Full Standards Certification. 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.
- 6.5. 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.

7. Data protection

- 7.1. The Parties agree that all personal data processed in the performance of this Certification Agreement will be protected in accordance with the Data Use and Transmission Agreement in place between the parties. The Data Use and Transmission 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 certification and other means necessary to govern registry operations. The following data protection clauses provide additional requirements beyond those specified in the Data Use Agreement:
- 7.2. The sending of data is obligatory. 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 (found in [WMDA Share](#)).
- 7.3. 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.
- 7.4. WMDA will maintain data acquired throughout and relevant to the application and renewal process for two (2) completed application cycles with a minimum of eight (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.
- 7.5. The WMDA processes data to fulfil its duties as conferred under the WMDA Certification Scheme. This can mean that WMDA shares data with evaluators or other representatives of the Certification Body as

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required to make a decision with regard to Benchmark L1 / Benchmark L2 / Full Standards Certification. WMDA also shares data with bodies that are auditing the WMDA Certification Body.

8. Suspension, complaints and dispute resolutions


- 8.1. WMDA may terminate or suspend Benchmark L1 / Benchmark L2 / Full Standards Certification based on the findings from evaluations obtained during the period of Benchmark L1 / Benchmark L2 / Full Standards Certification or based on findings arising from a complaint. The policies and procedures for investigation of complaints and suspension/termination are described in [WMDA Share](#).
- 8.2. Registry may request that a decision to disapprove WMDA Benchmark L1 / Benchmark L2 / Full Standards Certification 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](#).
- 8.3. 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 evaluators during any audit.

9. Fees

- 9.1. A fee is charged upon filing a Letter of Intent to apply for WMDA Benchmark L1 / Benchmark L2 certification. 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's website](#).
- 9.2. Registry does not pay for reviewer travel and lodging during on-site inspections required for certification.
- 9.3. After submitting a first application for Benchmark L1 / Benchmark L2 / Full Standards, an annual fee will be charged (maintenance certification fee). The fee is billed in January of each year on the annual WMDA invoice.
- 9.4. All fees applicable to the WMDA Certification Scheme are described publicly on the WMDA's website. WMDA may change these fees by giving one (1) months' notice.


10. Governing law and jurisdiction

- 10.1. 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.

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11. Liability, warranty disclaimer, indemnity

- 11.1. WMDA shall not in any circumstances have any liability for any losses or damages which may be suffered by Registry (or any person claiming under or through Registry), whether the same are suffered directly or indirectly or are immediate or consequential, and whether the same arise in contract (including warranties), tort (including negligence) or otherwise howsoever, which fall within any of the following categories:
- 11.1.1. Loss of profits,
 - 11.1.2. Loss of anticipated savings,
 - 11.1.3. Loss of business opportunity or any other repercussion attached especially to the granting, expiration, suspension, or withdrawal of certification,
 - 11.1.4. Loss of goodwill,
 - 11.1.5. Loss or corruption of data.
- 11.2. In any case the total liability of WMDA in connection with this Certification Agreement, whether in contract, tort or otherwise, shall in no circumstances exceed the sums actually paid by the Registry to WMDA in the 12 (twelve) months immediately preceding the damage-causing event.
- 11.3. The exclusions and limitations of liability referred to in clauses 11.1 to 11.2 also apply to indemnification obligations (*vrijwaringsverplichtingen*) and obligations to undo or restore received performances (*ongedaanmakingsverbintenissen*). The exclusions and limitations of liability referred to in clauses 11.1 to 11.2 shall apply to the fullest extent permissible by law, but cease to apply if and insofar damage is caused by intent or deliberate recklessness on the part of WMDA's management;
- 11.4. The right to compensation of damages exclusively arises if the Registry reports the damage to WMDA in writing as soon as possible after the damage has occurred. A claim for compensation for damages against WMDA must be filed no later than twelve months after the Registry has discovered or could reasonably have discovered the damage, failing which the right to compensation for damages will lapse (*vervallen*) unless the Registry has instituted a legal action for damages prior to the expiry of this term.
- 11.5. A grant of Benchmark L1 / Benchmark L2 / Full Standards Certification by WMDA is recognition of the Registry's performance based on a sampling of the available records at the time of application; Benchmark L1 / Benchmark L2 / Full Standards Certification by WMDA does not constitute a warranty of complete or continuous compliance. The Registry is solely responsible for the selection and representativeness of the samples to be examined, unless expressly agreed otherwise. All services provided by WMDA are performed on the basis of a best-efforts obligation (*inspanningsverbintenis*) unless and insofar as WMDA has explicitly promised a result that is described in a sufficiently precise manner. In addition, WMDA does not guarantee that WMDA certification will be accepted by any third party for **{ION/WACC}**


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reimbursement purposes. The Registry is solely responsible for ensuring the quality and safety of its products and services and determining the reimbursement requirements applicable to it.

- 11.6. Registry shall indemnify and hold harmless WMDA, its employees, contractors, suppliers, agents, WMDA evaluators, members of the WMDA Certification Committee and other affiliated partners and persons (each a 'WMDA Indemnitee') from and against any and all liability, loss, cost, expense, damage, claims or demands, including reasonable attorneys' and expert fees, incurred by or demanded from any WMDA Indemnitee by or on behalf of any third party in connection with any clinical intervention or procedure performed at the sites that are or were part of a certification process under this Certification Agreement.
- 11.7. The exclusion and limitation of liability, disclaimer of warranty and indemnity shall survive the termination or expiration of this Certification Agreement.

12. Duration and termination of Certification Agreement

- 12.1. 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 Registry.
- 12.2. WMDA is entitled to terminate this Certification Agreement with immediate effect by giving written notice to Registry if Registry does not or not fully perform one or more of its obligations arising from the WMDA Certification Scheme or this Certification Agreement.
- 12.3. Registry is entitled to terminate this Certification Agreement with immediate effect by giving written notice to WMDA.

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Thus, agreed and signed electronically

Signature Authorised Representative of Registry

Date: _____

Printed Name Authorised Representative of Registry

Signature Authorised Representative of WMDA

Date: _____

Printed Name Authorised Representative of WMDA