

DETAILS ORGANISATION RESPONSIBLE FOR HUMAN APPLICATION (OHRA)

| | | | |
|---|--|-------------------|--|
| First Name: | | Last name: | |
| Work Email | * Email address at hospital or institution. The address should be personal. A private or group email address cannot be used. | | |
| Complete function and hospital/institution: as fully as possible. These details are necessary in order to assure the end-user is an authorized health care professional. | | | |
| Organization | | Department | |
| Position | | BIG number | |
| Adress | | Zip code | |
| City | | Country | |
| Telephone Number | *The telephone number: a number at your hospital or institution, not a private number | | |

WHAT HAPPENS WITH YOUR DETAILS?

The provided details are used to;

- determine whether you are an authorised health care professional,
- assure traceability of the tissue products to the OHRA,
- have contact information available in case of a recall.

The details are for internal registration of approved OHRA only and will not be passed on to third parties before prior approval!

SIGNATURE

By signing this form I declare the following;

1. The Details are provided are filled in truthfully and the BIG registration number is Valid
2. I agree that the details I provided are used as described in this form.
3. I Am aware of the following responsibilities and facts;
 - a. Tissue products should be stored under secured storage conditions in a monitored space, in accordance with the instructions in the instructions for use.
 - b. In connection with traceability, the end user is obliged to register for which patient the tissue has been used and that the end user must keep this information and keep this information accessible for 30 (thirty) years after transplantation.
 - c. The end uses is legally obliged to report a serious adverse reactions / event (SARE).
 - d. Notification of changes to employment contract/function or hospital should be made to Medical Bone – Mr. P. van Weert peter@medicalbone.nl.
 - e. The Tissue products are ‘for single use’ only.
 - f. Tissue products cannot be returned.
 - g. Tissue products can not be distributed to third parties

End-user / OHRA

Date & Signature:

Tissue Establishment

OHRA Approved by TE, date & Signature