

26 July 2021

RFP 503342 Manual wheelchairs, wheelchair seat cushions and wheelchair accessories for UNICEF and WHO programmes and partners

CLARIFICATIONS - round 3 - to question received from suppliers:

- 1. We have a low-cost cushion which does not hold the mandatory certifications, are we still able to submit this for evaluation?**

Yes, but please submit the following mandatory test report with the bid for the cushion: modified ISO 16840-2:2018 loaded contour depth and overload tests. Both the test equipment and tests are simple. The test equipment can be built by the manufacturer/supplier/bidder, and the tests can also be performed, and the report generated locally by the manufacturer/supplier/bidder. Refer to Annex D_ISO 16840_Modified_Wheelchair_cushion_testing_protocol.pdf which is part of the RFP bundle.

- 2. In the event of returned goods, will there be RMA verification process prior to goods being returned?**

UNICEF has a claims handling system in place where we verify claims issued by our UNICEF Country Offices and/or partners. This process is managed from UNICEF Supply Division (SD) in Copenhagen who is responsible for the LTAs established with suppliers. Communication between the parties would therefore be managed by SD. If an inspection is required, for instance, UNICEF will request for a Pre-Delivery Inspection (PDI) which is conducted by well established companies pre-selected and contracted by UNICEF. These inspections normally take place at the supplier manufacturing site. A formal report is drafted and shared with UNICEF. If any issues are highlighted, UNICEF will then share the report with the supplier and ask for comments and corrective actions. If UNICEF receives a complaint from a partner after the goods have been delivered, a formal report including pictures/documentation is requested. The report is then shared with the supplier for comments and suggestions on how to move forward.

- 3. Will goods be consolidated at a specific continent for supplier to pick-up? Or will it be shipped back to the original shipping port of transfer?**

If there is a documented issue with a product delivered by a supplier, and it is agreed that the product needs to be returned, the supplier needs to ensure and pay for pick-up and return.

- 4. Will there be a specific amount of time to complete the RMA process?**

No, but in reasonable time.

- 5. How will RMAs be handled?**

Please see description of process under question 2.

- 6. Our products are properly CE-marked under CE 93/42. The products are Class I medical devices, they are self-declared, so no external certification is needed by the EU. Our manufacturing plant is ISO 13485 audited and certified, we have complete technical files and our manufacturer self-declares conformity, as allowed by CE 93/42. In your document, you ask for "market release certificates" to show clearance by the EU (for example), but these are not appropriate for our products, as there is no requirement for certification by any Notified Bodies for Class I MD. Additionally, the wording in**

paragraph 3 on page 23, the first sentence uses the phrase “strongly recommended” and the second sentence uses the word “requirement” which is confusing.

We are fully compliant with CE 93/42, but cannot provide the market release certificate as your requirements state – is our manufacturer’s self-declaration letter of conformity sufficient?

UNICEF will give preference to suppliers with at least one of the mentioned market clearances, but it will not be a mandatory requirement. It should be noted that if a supplier is selected and awarded an LTA without holding a valid market clearance from at least one of the mentioned areas, it may result in an inability to sell products to select countries in which clearance certification is a requirement for import. For that reason, if a company without at least one of the mentioned market clearances is awarded the LTA, UNICEF will actively advocate for the supplier to obtain one of the market clearances as demand for the products increase – guidance and support will be offered if needed.

- 7. Some countries require a Pre-Export Certification for import custom clearance, which must be obtained before the goods are shipped. We assume UNICEF would meet this cost as we believe it is the buyer’s responsibility under FCA? Also, the time taken to get this certification is out of our control, we assume that there would be no financial penalty for any shipment delayed by waiting for this certification.**

This is correct. Indeed PVoC, PDI etc. is not part of the FCA obligations, so yes it would be for the buyer’s account. There shouldn’t be any cost involved, as it needs to be done at the supplier’s premises, so storage should not apply.

- 8. Some countries require a certificate of origin for import clearance purposes. If required, we assume we can invoice this?**

Please see answer under question 19 below.

- 9. You allow MOQs to be specified for each product. However, in many instances, our costs (and the prices we charge) are per-order, or depend on the total number of products in the order. Your template does not seem to allow for any per-order charges, or for a minimum order value. For example, we will need to meet the cost of shipment from factory to port, which is fine for larger orders, but less so for smaller ones (say under \$10,000).**

How can we specify this detail in pricing? Should we wait until the detailed negotiations post-award if we are successful, or should it form part of our proposal? A minimum order value would be a very useful thing to add, and would have the effect of reducing unit prices for palletised shipments

Please specify the MOQ per each item in the commercial information sheet/form and also provide information separately (in the email submission or as a separate attachment) if other options such as minimum order value apply.

- 10. We have a children’s chair we want to submit (40, 60 and 70). As this is a small children’s chair, should the requirement for 2 rear wheel positions be mandatory? After research and consultation with users and clinicians, we have set the rear position in a safe setting with anti-tipper to allow safe use over uneven terrain for all children in the weight/size range. Currently, this would exclude us from bidding in some of these categories. Can you confirm that this would not be a pass/fail for a children’s chair?**

With the aim to optimise user access to the rear wheel, propulsion ergonomics, optimise stability and mobility and postural alignment whilst propelling, UNICEF requires an adjustable rear wheel position for all active wheelchairs. As this is a Request for Proposal (RFP), you may, propose products which do

not fully meet all specifications. However, UNICEF will give preference to those products meeting all mandatory and other general specifications.

11. Some fields of the document enable text to be added but not later amended and are password protected.

- **Could the password be supplied? This includes but not limited to:-**
- **Annex B.1, Worksheet 10, line 14, column D**
- **Annex B.1, Worksheet 20, line 145, column D**
- **Annex B.1, Worksheet 40, line 73, column D**

We have checked the original document again and were not able to produce the same errors as reported. We suggest that you download the original document again and copy and paste information over to the new document.

12. How much minimum order quantity? I.e. is it one container of 2 feet for each model? or not less than 100 units for each?

Please provide MOQ in units not containers. Please indicate in the proposal in the Commercial Information Sheet what your minimum order quantity is. Please also indicate the FCA palletized costs for the products offered.

13. Is the price fixed for 3 years contract? As you are aware that the raw material's prices are increasing every year worldwide. Except the quantities for the three years is known.

UNICEF prefers to award LTAs with fixed prices for the duration of the contract. Suppliers need to try and foresee any market fluctuation for the LTA awarded period and incorporate/calculate this in the proposed prices. The reason for this is that UNICEF needs to have visibility and predictability for the duration of our LTAs in order to be able to communicate with partners, budget accordingly etc. It is also very time and resource consuming for UNICEF to amend LTAs with suppliers. In exceptional cases UNICEF may agree to review a supplier's request to amend prices during the LTA period if there are unforeseen reasons for such and if the increase is properly justified. Depending on the price increase, context and justification, UNICEF may decide that this is not acceptable and terminate the LTA with the supplier, but this would be done through a process of communication and clarification with the supplier.

14. The Eid holiday is approaching, the remaining time is insufficient to get a proper offer with all details. Its highly appreciated if you extend the deadline.

The deadline has already been extended once. There are no plans to further extend the deadline.

15. In Category 50 (active dual-terrain folding w/c), there is a pass/fail test for a tension adjustable back support. This would exclude a solid backrest. Was that really your intention, as we are not aware of a clinical reason for this?

In line with the WHO assistive device specification guidelines, a tension adjustable backrest was selected to provide minimum degree of postural support to a large range of users, at little additional weight and cost, and to meet all the other requirements of back height adjustability/replacement with solid backrest. Not all users require a solid backrest, and the type of solid backrest provided on any particular wheelchair may not be appropriate to all users. This is a RFP and if your proposed solid

backrest and wheelchair design meets all the functional and postural requirements of a tension adjustable backrest, it will be assessed accordingly. UNICEF will give preference to those products meeting all mandatory and other general specifications.

16. In Category 70 (active rough terrain), you ask for adjustable seat width. Does this exclude adapting for different widths by the use of seat restriction kits/hip pads?

Please note that we do not specifically require a width-adjustable seat. Seat width options may include either different size (width) wheelchairs or width-adjustable frame (line 76). Mechanism for seat width range adjustment must be provided in line 80 in Annex B.1 for this item. Adjustments should be practical, safe and allow for optimal function and posture support.

17. In Cat 20 (active, urban, fold, more support), you seem to exclude products that have adjustable backrest straps. Was this your intention? Is so, is there a clinical driver for this? We might possibly understand this in a more supportive wheelchair, but this pass/fail is also in CAT 30.

A tension adjustable backrest is a mandatory requirement for items 20 to 60 (in Annex B.1). The adjustability of the straps provides the necessary customised set-up for posture support. Alternative tension adjustable designs, which provides similar functionality as tension adjustable backrests, will be assessed and scored on function and effectiveness.

18. Would you accept the supplier to include order handling charges and bank charges as separate items in the invoice to UNICEF or should they be included in the product price?

All costs related to delivering the goods FCA nearest international sea/airport should be included in the item price.

19. If additional certifications and documentation is required on an order (ex. Certificate of origin), would UNICEF accept these additional charges to be included in the invoice as separate items?

The supplier should provide the necessary shipping documents and other supporting documents as specified in section 2.1 paragraph (c) under [UNICEF packing requirements](#) : itemised invoice for the Goods in the consignment(s); copies of packing list (where available); and any other document/certificate required for export/import of goods. Normally, certificates of origin may be requested in instances where items are produced in countries other than that of the Proposer.

Normally, it is enough that the Proposer is stating the country of origin, but in some instances the Proposers may be required to submit a Certificate of Origin of Goods issued by the Chamber of Commerce or other equivalent authority. In these cases UNICEF expects that the supplier would incur these costs.

20. For the category 80 (wheelchair postural support), a tilt range of 20 degrees is required, and is stated pass/fail. What is the reason for this? We could accept that 20 degrees might be preferable to 15 degrees (although this is not our experience), but surely this should be scored not pass/fail.

In line with the WHO assistive device specification guidelines, UNICEF selected this range as a suggested minimum required range for users requiring variable tilt for clinical and functional reasons. As this is a RFP, products with lesser range may be proposed. UNICEF, however, will give preference to those products meeting all mandatory and other general specifications.

21. After reviewing the Annex B.1_Wheelchairs_Technical Information Sheet, we are confused for the requirement "For safest setting, the rear wheel should be able to be aligned behind the line of the back post attachment on seat rail." could you kindly clarify it ?

In wheelchairs where the seat to backrest angle can be opened up (refer Figure 3 of technical illustrations in Annex B.1), the center of gravity is moved backwards.



Figure 3

The rear wheel/seat must be horizontally adjustable (refer Figure 2 of technical illustrations in Annex B.1) to maintain stability and optimal access to the rear wheel.

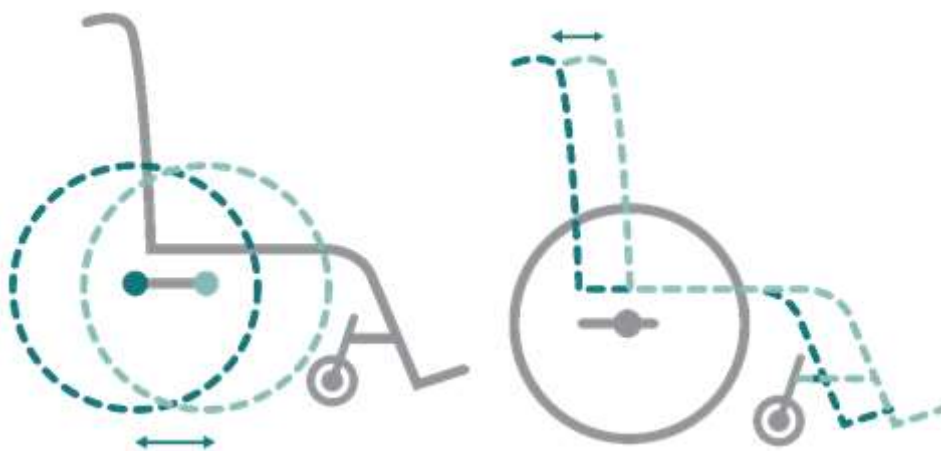


Figure 2

In the left-hand illustration, the darker wheel, wheel position shows the safest setting with the rear wheel behind the back post attachment to the seat rail. In the right-hand illustration, the lighter frame position shows the safest rear wheel setting with the rear wheel behind the back post attachment to the seat rail.

22. For images displaying the product: can those be sent as a JPEG, instead of PDF/Excel? Please confirm. Yes, any common graphic format such as JPEG, PNG, etc. is acceptable, as long as images are clear and good quality.

23. With regard to requirements for marketing clearance, Line 27:

Does the product comply with regulatory requirements for marketing clearance, for example: Australia: TGA Device License, Device License (Canada, Japan, New Zealand), CE 93/42 Medical Device Directive (MDD) Mark, USA 510k market clearance? For further info refer to para 4./ in the Technical Provisions document.

The CE93/42 Medical Device Directive has been superseded by the MDR on the 26th of May 2021. Although still recognized in the UK and CH for a few more years, we have all our products MDR compliant. The way we have approached it is as following:

- We answer the question with NO**
- On the question below (line 29), we answer it with YES**

*** If not complying with any of the above market clearance, does the manufacturer comply with any other national/regional/international market clearance/device license?**

- And in the next line for:**

*** If YES, SPECIFY and provide expiry date. Attach certificate.**

**We specified MDR compliance, expiry date, and document name.
Can you confirm this is acceptable?**

This is not correct. Please answer YES for line 27. The listed marketing clearance standards are only examples. Both MDR and MDD are acceptable. In line 28, specify the type of market clearance and expiry date, and attach the certificate.

24. After getting access to the SharePoint, may I assume that uploading the docs is replacing the email to supplybid@unicef.org? Or do all documents need to be submitted per email AND SharePoint? Please confirm.

It is enough that your proposal is being submitted in the SharePoint folder(s) that UNICEF will provide to you at your request. You do not need to submit to both the SharePoint folder and email address supplybid@unicef.org.

25. I am unable to find the Solicitation Document number. Or is this RFP-DAN-2021-503342? Please let me know.

Yes, the UNICEF solicitation document number is **RFP-DAN-2021-503342**.

26. On page 23, the tender states that if not in place at the proposal stage, market clearance needs to be obtained by the award stage. a. Australia: TGA Device Licence; b. Canada: Device Licence; c. European Union: CE 93/42 EEC Medical Devices Directive (MDD) Mark; d. Japan: Device Licence; e. USA: 510k market clearance. While it is not unusual for products within the LMIC sector to be produced - most commonly - to CE standards and to display the relevant markings; it is unlikely that they are cleared for market release in the HICs listed in the tender and instead offer self-declaration certificates of compliance. Per WHO's guidelines on the provision of manual wheelchairs in less-resourced settings, the ISO 7176 Series are appropriate standards that governments can adopt as national standards to evaluate the functional performance of wheelchairs. Would UNICEF consider the ISO standards (or equivalent), including ISO13485 (Quality management for Medical Devices), ISO7176 (Wheelchairs – parts 1, 8 and 11 are the most relevant) and ISO16840 (cushions and PSDs) on their own instead of in combination with market clearance?

UNICEF will give preference to suppliers with at least one of the mentioned market clearances, but it will not be a mandatory requirement. It should be noted that if a supplier is selected and awarded an LTA without holding a valid market clearance from at least one of the mentioned areas, it may result in an inability to sell products to select countries in which clearance certification is a requirement for import. For that reason, if a company without at least one of the mentioned market clearances is awarded the LTA, UNICEF will actively advocate for the supplier to obtain one of the market clearances as demand for products increase – guidance and support will be offered if needed.

27. For selected products that do not have the full ISO-suite, will UNICEF allow for additional time to complete relevant ISO testing?

Mandatory standards should be in place at time of submission. All standards should be in place at the time of award.

28. Many high-quality, assistive products designed for LMIC markets that have proven their quality, durability, and appropriateness do not have the market clearances outlined on page 23 of the tender document. The countries issuing the market clearances are not the target markets for these products because they generally have robust health care systems and a diverse selection of wheelchair manufacturers that distribute AT. Obtaining market clearance is a lengthy and expensive process. If a product without the required market clearances is selected, will UNICEF guarantee execution of an LTA-G once one or more of those clearances are obtained?

UNICEF will give preference to suppliers with at least one of the mentioned market clearances, but it will not be a mandatory requirement. It should be noted that if a supplier is selected and awarded an LTA without holding a valid market clearance from at least one of the mentioned areas, it may result in an inability to sell products to select countries in which clearance certification is a requirement for import. For that reason, if a company without at least one of the mentioned market clearances is awarded the LTA, UNICEF will actively advocate for the supplier to obtain one of the market clearances as demand for the products increase – guidance and support will be offered if needed.

29. In worksheets 20 and 30, you state that a quick release mechanism for seat-to-back angle is not acceptable (Fail). We do not understand the rationale for this. Could you remove the pass/fail rating?

The rationale for a tool adjustment is for durability and stability. As this is a RFP, products with different specifications can be proposed. UNICEF, however, will give preference to those products meeting all mandatory and other general specifications.

30. Worksheet 80 requires ISO 16840-2:2018 loaded contour depth and overload tests. One of our products has an integrated cushion which are primarily for support rather than pressure relief - does that mean that it's excluded?

The loaded contour depth and overload tests also apply to posture support cushions. This test can be performed, and report produced by the manufacturer/supplier. The seat cushion should be removable to allow individual customising and fitting as needed. As this is a RFP, products with different specifications can be proposed. UNICEF, however, will give preference to those products meeting all mandatory and other general specifications.

31. Please clarify the meaning or purpose of the request for “frame weight”. Is this the weight of the metal frame, or the weight of the wheelchair with all removable components removed (e.g. as might be used for transport)?

The frame weight for items 20 to 60 in Annex B.1 is specified under Wheelchair weight as the weight of the frame without removable components, such as arm- and foot supports, and rear wheels.

32. We have a young child's seat that does not have wheels but does provide postural support. Is this outside this current RFP?

Unfortunately, static posture support seats fall outside the scope of this tender.

33. UNICEF has received some questions related to changes/amendments of our General Terms and Conditions. Below are our comments.

UNICEF's terms and conditions are standardized and apply to all global suppliers being awarded following a tender process. The terms and conditions are carried over from the tendering process through the awarded LTAs. In line with the principles of public procurement of transparency and fairness to all suppliers, the same terms and conditions must apply to all awards and subsequent contracts and cannot in principle be individually negotiated. UNICEF has thousands of active LTAs with thousands of suppliers all around the globe. Engaging on negotiations on specific clauses for each contract with each supplier would moreover require huge resources from UNICEF. However, should a supplier have any comments to our terms and conditions it is recommended that they highlight this in their proposal. Should the supplier be recommended for an award, UNICEF can arrange for a specific call to discuss and address supplier's concerns.

34. Our articles are very small, most items do not weigh more than 200 grams and the cost is also low(er) compared to the cost of the wheelchairs. In the tender document there is a request for prices based on pallet delivery to the airport. You can understand that delivering or products such as seat belts on a pallet will drive the cost of the products extraordinary up or the MOQ's need to be so large, it will be a struggle to keep costs "manageable" at best. Alternatively, we have to establish a minimum order amount (likely to minimum of 2.000-3.000\$) and even then the chances are that you will end up with a small 30x50x40cm (W x L x H) box strapped down to a 100x80cm pallet that could easily hold 10 times more product. The costs of the pick-up of a pallet and delivery to the airport are significantly higher compared to a carton box we always use for all our international shipments. Costs we have to factor in in the price-offer.

Question: for WHO/UNICEF it would be much more cost effective and will drive the MOQ's down if we are allowed to use boxes instead of pallets. Can you please let me know if this is possible to consider?

For tender evaluation purposes and ensuing LTAs, we need FCA palletized prices. However, it is correct that for actual orders, for certain commodities with small volumes and weights, one or a few small boxes or envelopes will be used (and not pallets).

35. Annex C, the Volume and Weight figures. I assume these are per box, but bear in mind that for, say, straps, they are boxed in 20s and we have given the volume of the full box. Are we able to change the UoM to boxes of 20 instead of each?

Yes.