



Ref: PQ 36852/24

10th October 2024

Deputy Paul Murphy
Dáil Eireann
Dublin 2

Dear Deputy Murphy

I refer to your below parliamentary question which has been forwarded to me for attention.

PQ 36852/24 – To ask the Minister for Health the details on the procurement of the halo gravity traction chairs currently in use or which have been in use over the past several years at Children's Health Ireland, including the brand, make, model, and supplier of the chairs; and whether these chairs were procured in compliance with Medical Device Regulations (EU) 2017/745, in tabular form.

Children's Health Ireland (CHI) Response:

March 2024 - Present

Children's Health Ireland **currently has two** halo traction wheelchairs.

Manufacturer:	Medicalex
Model number:	56.512.20
Model Name:	Halo traction system for wheel chair
Size:	Medium

- CHI has 1 device of this model currently.
- It is a rental device.
- This device was rented on the 9/08/2024 and will remain in use until the newly procured chairs go into service.

Manufacturer:	X-Med AB
Model number:	20112006
Model Name:	Align Halo Gravity Traction Wheelchair
Size:	Size 6

- CHI has 1 device of this model.
- Purchased on 18/09/2024.
- Put into use on the 12/09/2024 (used on a trail before purchase)



Manufacturer:	Medicalex
Model number:	56.512.20
Model Name:	Halo traction system for wheel chair
Size:	Medium

- CHI awaits delivery of two of these devices. We expect to receive the delivery at the end of October.

Manufacturer:	X-Med AB
Model number:	20112006
Model Name:	Align Halo Gravity Traction Wheelchair
Size:	Size 5

- CHI awaits delivery of one of these devices. We expect to receive the delivery by the end of November.

Prior to March 2024:

2 halo gravity wheelchair *systems* were in use prior to March 2024.

CHI at Crumlin

Prior to 2024, CHI at Crumlin used "Rota" wheelchairs.

Manufacturer:	Delta Orthopaedic LTD
Model:	Rota Wheelchairs
Size:	Small and medium

- No procurement details exist for these wheelchairs.
- No information is available in relation to MDR compliance.
- Due to the age and condition of the chairs, they were decommissioned.

CHI at Temple Street

Prior to 2024, halo traction in CHI at Temple Street was provided using CE-certified wheelchairs, which were adapted to provide halo traction.

Manufacturer:	Ottobock
Model:	Start M6
Size:	Sizes 12 – 18 inches

- The mechanical components for the halo traction were manufactured by an engineering company, from the specifications given to them by the hospital. Devices were assembled by the hospital and fixed to the wheelchairs.
- While the wheelchairs were CE marked, the adapted system as a whole did not have a CE certificate and was not in compliance with the MDR 2017/745.
- These devices have been decommissioned.

Sláinte Leanaí Éireann



Children's Health Ireland

Sláinte Leanaí Éireann (SLÉ), Herberton, Siúlán San Séamas, Rialto, D08 HP97, Éire
Children's Health Ireland (CHI), Herberton, St James's Walk, Rialto, D08 HP97 Ireland

Yours sincerely

Mr. Stephen Flanagan
Acting Deputy CEO
stephen.flanagan@childrenshealthireland.ie

Our **Mission** is to: Promote and provide child-centred, research-led and learning informed healthcare, to the highest standards of safety and excellence. We will do this in partnership with each other, with children, young people and their families through a network of children's services in Ireland.

CRA Registered Charity Number (RCN): 20202295 Revenue Charitable Status CHY: 22235

Board Members: Prof James Browne (Chairman), Mr Con Cronin, Ms Mary Cryan, Ms Mary Donovan, Prof Martin Elliott, Ms Catherine Guy, Dr Gavin Lavery, Mr Bernard McLoughlin, Ms Brigid McManus, Ms Eleanor O'Neill

Sláinte Leanaí Éireann



Children's Health Ireland

Sláinte Leanaí Éireann (SLÉ), Herberton, Siúlán San Séamas, Rialto, D08 HP97, Éire
Children's Health Ireland (CHI), Herberton, St James's Walk, Rialto, D08 HP97 Ireland

Our Mission is to: Promote and provide child-centred, research-led and learning informed healthcare, to the highest standards of safety and excellence. We will do this in partnership with each other, with children, young people and their families through a network of children's services in Ireland.

CRA Registered Charity Number (RCN): 20202295 **Revenue Charitable Status CHY:** 22235

Board Members: Prof James Browne (Chairman), Mr Con Cronin, Ms Mary Cryan, Ms Mary Donovan, Prof Martin Elliott, Ms Catherine Guy, Dr Gavin Lavery, Mr Bernard McLoughlin, Ms Brigid McManus, Ms Eleanor O'Neill