PUMP

harvesthealthcare®

General User/Safety Guide

HARVEST 3 PUMP

www.harvesthealthcare.co.uk

CE

CONTENTS

WARNINGS & CAUTIONS

READ THIS INSTRUCTION MANUAL AND OBSERVE SAFETY INSTRUCTIONS.

⚠ WARNING

- This pump must be properly installed and operated as directed by this user manual.
- The pump should be checked regularly to ensure correct operation. Loss of function will remove all pressure relieving properties.
- This pump, when connected to a pressure relieving system, is intended for use as part of a pressure ulcer prevention program; do not rely solely on this device to achieve the result. The medical professional is responsible for applying best medical judgment when using this system.
- Select the correct setting for the occupant's weight and therapy required. Care should be taken not to accidently change pressures once set as the effectiveness of the therapy may be reduced.
- All hoses must be free of kinks, twists and must be properly connected and positioned so as not to cause any obstruction.
- Do not position the pump in a way that prevents access to the disconnection device (mains power plug).
- Ensure the mains lead or pump cannot become trapped or crushed, e.g. by raising or lowering of bed or bed rails or any other moving object.
- Check the mains lead is damage free and positioned so as not to cause an obstruction or injury e.g. strangulation or trip hazard.
- Ensure that the electricity supply is of the type stated on the pump unit.
- Do not place pump on or near a heat source or cover with bedding.
- Harvest Healthcare advise against smoking whilst the system is in use to prevent the accidental ignition of associated items which may be flammable, such as bed linen. We advise a risk assessment is carried out before using any medical equipment to protect the user and service user.

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WARNINGS & CAUTIONS

- Do not expose the pump to liquids.
- Wireless equipment such as mobile phones should be kept at least 10ft/3m away from the system.
- The mattress/cushion and pump should be cleaned between patient uses.
- Do not use bleach, chlorine releasing agents in concentrations over 1000 ppm, solvents or alcohol-based cleansers, e.g. Phenicol, Hibiscrub, Clearsol, Stericol and Hycoline as these will destroy the mattress material. Full cleaning instructions can be found on **page 15**.
- Suitable for continuous use.
- Do not modify the mattress/cushion or pump unit in any way.
- Do not connect to any other medical device or equipment.
- Not for use in an oxygen enriched environment.
- Not for use in an outdoor environment.
- Store the system in a clean and dry environment, out of direct sunlight.

Electrical equipment can be hazardous. Only authorised technical personnel should remove the rear pump case for maintenance. Removal of the case by unqualified personnel will invalidate the warranty.

Before cleaning the unit ensure that the electrical supply to the pump has been disconnected by removing the plug from the power supply.

GENERAL INFORMATION

BEFORE USING THIS SYSTEM FOR THE FIRST TIME:

- **Read through this instruction manual conscientiously from start to finish.**
- **Note the safety instructions which must be observed.**

Harvest Healthcare products bear the CE mark and meet all safety and functionality requirements.
These safety requirements can only be met if the user is satisfied with the proper condition of the product (including accessories) before use.

GENERAL INFORMATION

Harvest 3 is our high end, digital pump designed to provide controlled compressed air to a pressure care mattress or active seat cushion. The inflated cells within the supplied mattress provide an alternating pressure surface designed to reduce surface pressure on the skin and therefore reduce risk of the development of pressure ulcers in susceptable patients.

The Harvest 3 provides the highest air pressure of the Harvest Healthcare pump range and therefore outputs suitable flow for all use with all Harvest Healthcare active pressure care mattresses. This includes use with bariatric products, and for occupants with more complicated clinical needs.

This pump has audible and visual alarms for low pressure, power failure and cycle fault, static mode and a lock out facility. Extra features include maxi firm mode, seat inflate mode and four choices of cycle time - 10, 15, 20 and 25 minutes.

Harvest Healthcare supply a pump and mattress but it is the user's responsibility to ensure each system meets the guidelines set out in the pump and mattress guide (shown below). Failure to do this could put the service user at risk. This could prolong the recovery process or increase the risk of further tissue damage.

For information on our mattress range please refer to the mattress user manuals available on our website www.harvesthealthcare.co.uk.

	Harvest 1	Harvest 2	Harvest 3
Kensington Overlay	✓	✓	✓
Sandringham	✓	✓	✓
Hampton	✓	✓	✓
Windsor	×	✓	✓
Hampton Extra	×	×	✓
Prime Comfort Active	✓	✓	✓
Duke	×	✓	✓
Duke Extra	×	×	✓

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GENERAL INFORMATION

1 DEFINITION OF THE GROUPS MENTIONED

OPERATOR

An operator is any natural or legal person who uses the equipment or on whose instruction it is used (e.g. nursing homes, specialised retailers, health insurance companies, medical suppliers).

USER/CARE PERSONNEL

Users are persons who as a result of their vocational training, experience or briefing are authorised to operate the equipment.
Furthermore, the user/care personnel can recognise and avoid potential dangers and assess the clinical condition of the service user.

PATIENT/OCCUPANT/SERVICE USER

The person in need of pressure care support, due to being identified as at risk of developing of pressure ulcers by a suitably qualified carer or other.

QUALIFIED PERSONNEL

Qualified personnel are employees of the operator who as a result of their vocational training or briefing are entitled to deliver, assemble, disassemble and transport the product.

2 NON-COMPLIANT USE

All uses deviating from the intended purpose, which may also be hazardous as a result. This includes for example:

- Incorrect installation.
- Operation by persons who have not been instructed in its use.
- Using the system with non-approved parts/accessories.
- Using the system if any of the components are damaged or faulty.

3 SAFETY INSTRUCTIONS

3.1 GENERAL SAFETY INSTRUCTIONS

During the briefing, specific attention must be drawn to any potential dangers which can occur despite correct operation. Before putting the product into service for the first time, the Instruction Manual must be read conscientiously and in detail by the user/care personnel.

Programming of the system should be carried out by competent trained personnel. Use only spares and accessories supplied or approved by Harvest Healthcare. Only suitably trained personnel are allowed to operate the system.

GENERAL INFORMATION

The mains cable must be free and not be allowed to be caught up in the bed's moving mechanisms. The mains cable may be damaged or it may be pulled out of its socket and electric leads exposed as a result.

If the mains cable or the mains plug are damaged, the relevant part must be replaced. This work should be carried out by the manufacturer or authorised service agents.

When connecting the mains plug do not use multiple sockets since liquids may penetrate into these (fire hazard and electric shock).

3.2 SAFETY INFORMATION FOR THE OPERATOR

With the help of this instruction manual, instruct each user in the safe operation of this system before it is put into service for the first time.

Advise the user of any hazards which may occur if not handled correctly.

Only persons who have been properly instructed may operate this system. This also applies for persons who only operate the system on a temporary basis.

3.3 SAFETY INFORMATION FOR THE USER

Ensure that the operator instructs you in the safe operation of this system.

In addition, pay particular attention to the 'Warnings and Cautions' (**page 4-5**) and the 'General Safety Information' as described in **3.1**.

If there is a suspected fault or damage, unplug the mains plug from the socket and follow the power down procedure (**page 16**). Clearly mark 'Out of Order', take out of service immediately and inform the person in charge without delay.

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GENERAL INFORMATION

3.4 SYMBOLS USED


This symbol indicates general hazards. There is a danger to life and health.


Conformity mark in accordance with the Medical Device Directive (93/42 EEC).


The symbol for Protection Class II device, double insulated.


The symbol for type B device according to EN 60601-1.


Handle with care.


This way up.


Keep dry.


Recycling symbol. Refers to packaging that can be recycled (cardboard).


Fragile, handle with care.


This product must be disposed of in a designated refuse bin for waste electronic devices (WEEE) in the European Union. Do not dispose of as normal domestic waste.


No smoking. No naked flames.


Read instructions / consult manufacturers guide.


This symbol indicates electrical hazards. There is danger to life and health.

GENERAL INFORMATION

3.5 CLEANING & DISINFECTION

Do not immerse electrical components in water but wipe with a damp cloth only. The electrical components must not be cleaned with a high-pressure cleaner or water jet. Disinfection by wiping only is allowed.

Full cleaning and disinfection instructions can be found on **page 15**.

3.6 SERVICING & MAINTENANCE

Servicing must only be carried out by qualified personnel.

A technical check and/or safety inspection must be conducted at least once a year or after a lengthy break in use.

Any defects, damage or signs of wear must be rectified without delay. Only original spare parts from Harvest Healthcare may be used, otherwise all guarantees or warranties will be invalidated.

See **pages 16-17** for 'Routine Maintenance' and 'Routine Servicing'.

3.7 SERVICE LIFE & DISPOSAL

The system must not be disposed of as normal domestic waste after its service life, but must be disposed of in a designated refuse bin for waste electronic devices (WEEE) in the European Union. Do not dispose of as normal domestic waste.

Our full terms & conditions including product warranties are available by request or can be found on our website **www.harvesthealthcare.co.uk.**

PARTS AND DATA MAY UNDERGO FURTHER DEVELOPMENT AND THEREFORE DEVIATE FROM THE DETAILS GIVEN.

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TECHNICAL SPECIFICATION

HARVEST 3 TECHNICAL SPECIFICATION

Pump Model No.	HPU3
Operating Cycle	10 / 15 / 20 / 25 minutes
Dimensions	340 x 125 x 244mm
Weight	3.5 kg
Air Flow Output	12 lpm
Pressure Setting	Manual

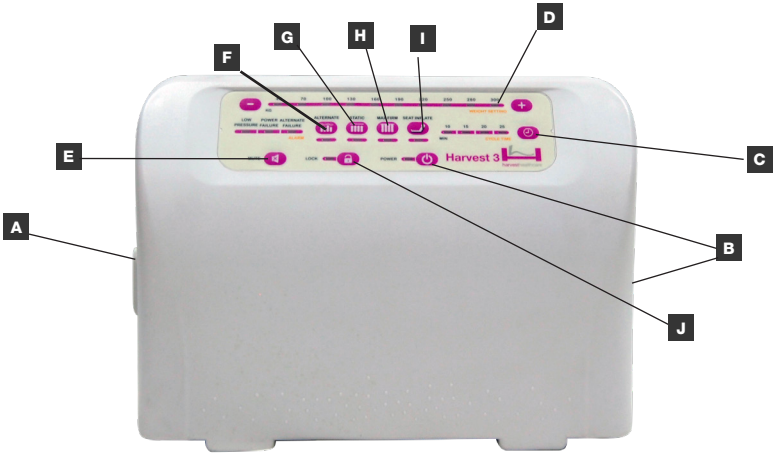
PUMP POWER REQUIREMENTS

Power Rating	13W
Voltage	AC 230V / 50Hz
Fuse	T 1AH 250V
Medical Classification	Type B Applied Part
Safety Standards	EN 60601-1. EN 60601-1-2

For any further assistance, please contact a member of the Harvest Servicing team at servicing@harvesthealthcare.co.uk

OVERVIEW

PUMP OVERVIEW



A	Feed Tube Connection	F	Alternating Mode
B	Power Switch	G	Static Mode
C	Cycle/Alternating Time	H	Maxi-Firm Mode
D	Pressure Range/Comfort Setting	I	Seat Inflate Mode
E	Alarm Mute	J	Lock Button

Maxi-Firm. This must be manually switched off after use.

A **Feed Tube Connector**
Pipes from the mattress connect here. The pump must be able to be disconnected in an emergency for CPR to be administered.

B **Power Switch**
The power switch is on the right hand side of the pump. When pressed to the ON position the switch will illuminate to indicate that there is a power supply to the pump. With the switch in the ON position press the power button on the control panel to activate the pump. To turn the pump off press the power switch on the control panel.

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OVERVIEW

C **Cycle/Alternating Time**
The cycle time can be selected by pressing the button on the control panel. The cycle time options are 10, 15, 20 or 25 minutes. Consult a medical professional for cycle times above ten minutes.

D **Pressure Range / Comfort Setting**
The pump has a scale printed on the front panel in kilograms. Press the comfort control button (-) or (+) until the nearest desired weight setting is illuminated on the display panel. When the mattress is in use the user can adjust the comfort setting as required for the service user's needs. A slight increase of the comfort setting may be required if the service user needs more support when the bed is profiled. When the bed platform is laid flat readjust the setting as required for the service user.

E **Alarm Mute**
The pump is fitted with an audible and visual alarm. Press the 'Mute' button to reset the alarm. Initially the alarm will sound after 40 mins if the mattress has not fully inflated while in the start-up mode. Once safely inflated the alarm will sound if it detects a cycle fault or low pressure fault on the system.

F **Alternating Mode**
When pump is switched on for the first time it will inflate all the cells.
The alternating mode LED will illuminate to indicate that the pump is in start-up mode. Once all the cells have been inflated the alternating mode will activate. The cells in the mattress will then inflate and deflated to prove pressure relief for the service user.

G **Static Mode**
The 'Static Mode' can be operated by the user to inflate all the cells for patient care and transfers. Press the 'Static Mode' button and the LED will illuminate orange. The 'Static Mode' will stop working after 20 mins and the pump reverts back to normal alternating mode.

H **Maxi-Firm Mode**
Press the 'Maxi-Firm' button to automatically inflate the mattress to its maximum pressure. This will take approximately 20 mins. During normal pressure operations the pump will monitor the pressures. **Switch off the Maxi-Firm after use.**

I **Seat Inflate Mode**
Press the 'Seat Inflate' button. The pump will increase the pressure by 5mmHg while this mode is activated. This function helps give the user extra support when the bed is profiled. No other settings need to be altered, either when in use or after deactivation.

J **Lock Button**
The 'Auto Lock Out' will become active after 5 minutes, signified by the LED green light next to the padlock symbol. This function prevents alteration of the pump settings. Deactivate the auto-lock by pressing and holding the padlock button.
The pump will bleep once and the LED light will extinguish. Access to the different functions will now be made available

K **Bed Hooks (Back of Pump)**
Attach the pump to the foot end of the bed. Adaptor brackets are available to fit different sizes of beds. If the pump cannot be attached to the foot end of the bed it is the user's responsibility to ensure that the pump is placed in such a position that it will not cause harm or injury to the service user. **The pump unit must be placed so that it can be clearly seen and monitored at all times.**

OPERATION

INFLATING THE MATTRESS/CUSHION

1 Plug in at the mains supply, press the ON button on the side of the pump and then on the control panel. The control panel will light up to indicate that there is a power supply.

2 The pump is in start up mode. Once the mattress is fully inflated it will be ready to use. **While in start up mode do not select static mode.** This will cause the pump to alarm. If the pump alarms, switch off the pump and switch it back on to reinflate the mattress.

The mattress is now ready to be used.

Set the pump to run at the correct pressure to suit the weight of the service user. Refer to the Pump Control Panel guide on the front of the pump.

To turn off the system press the power button to OFF and unplug from the mains supply.

TRANSPORT MODE

If the pump needs to be disconnected for any reason attach the transport cap to the feed tubes connector. This will prevent deflation retaining the remaining air within the mattress. **The alternating action stops in this mode.**

SETTING UP PROCEDURE

It is important to follow the correct setting up procedure to ensure the patient receives sufficient support whilst achieving maximum pressure relief and comfort.

Failure to follow this procedure could result in the patient being put at risk.

1 When the mattress is fully inflated set the pump to the approximate weight of the service user. Position the service user in the lying position. If required adjust the weight setting to meet the patient's comfort needs.

2 Ensure that the comfort setting is altered correctly when the patient moves from a lying to a sitting position and vice versa. This can be done using the 'Seat Inflate' button. The pump will increase the pressure by 5mmHg while this mode is activated. This function helps give the user extra support when the bed is profiled. No other settings need to be altered, either when in use or after deactivation

NOTE: The static mode is only to be used for patient care. Switch off after use.

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CLEANING & CARE

PUMPS

For general cleaning wipe with a soft cloth dampened with a mild detergent and water solution. This may be followed by either wiping with a sodium hypochlorite solution to a dilution of 1000ppm (parts per million) or by using alcohol wipes.

DO NOT USE HYPERCARBONATE, PHENOL-BASED CLEANING SOLUTIONS, ABRASIVE COMPOUNDS OR CLEANING PADS.

NOTES FOR CARE OF ASSOCIATED PRODUCTS

- Following the use of a detergent and/or disinfectant solution rinse the mattress cover with clean water using a clean cloth and allow to dry.
- Frequent or prolonged exposure to high concentrations of disinfectant solutions will reduce the useful life of the mattress cover.
- Where high concentration disinfectants e.g. > 10,000ppm chlorine releasing agent (e.g. Haztab or bleach) or combined cleaning/chlorine releasing agent (e.g. Chlorcleam, Actichlor) and detergent solutions are used to remove blood or other body fluids, mattresses should be thoroughly rinsed with clean water to remove any residues. This will help prevent any long term compatibility issues associated with disinfectant residues.
- Alternatively, disinfection may be achieved by laundering at temperatures not exceeding 80°C for 10 minutes which may include a chlorine rinse.

TRANSPORT & STORAGE

Storage conditions as follows:
–15 °C without relative humidity control and +40 °C at a relative humidity up to 93%, non-condensing. Atmospheric pressure range of 700 hPa to 1060 hPa. Suitable for all standard modes of transport when in the correct packaging.

Operation conditions:
A temperature range of +5 °C to +35 °C and relative humidity range of 15% to 93%, non-condensing. Operational atmospheric pressure 700 hPa to 1060 hPa. Suitable for pollution degree 2. Operational altitude ≤ 2000 m.

Transportation of the mattress system:
The mattress should be loosely rolled lengthwise with the cover innermost, taking care not to strain the feed pipes. It can then be stored / transported in the carry bag with the pump, mains cable and this booklet. Do not stack bagged mattresses more than two high.

ROUTINE MAINTENANCE

These checks should be carried out at each decontamination process, i.e. between patients or patient occupancy and weekly for longer term patients.

PUMP

1 Check the pump casing for cracks or other damage that could be dangerous.
2 Check the power cord (ensure there are no bare wires).

If any faults are detected remove the equipment from use and contact the Harvest Healthcare Service Department or your distributor.

OTHER COMPONENTS

- Check air cells and mattress interior for signs of damage or contamination, e.g. staining or fluid ingress at each decontamination process, i.e. between patients or patient occupancy (or weekly for longer term patients).
- The individual cells can be wiped clean with a mild antiseptic solution.
- All cells are replaceable and can be sourced from Harvest Healthcare.

POWER UNIT

Disconnect the power unit from the electricity supply before carrying out maintenance, repairs or cleaning.

Check all electrical connections and power lead for signs of wear and damage.
The power unit can be wiped down with a detergent or disinfectant solution. Do not use solvents. Unsuitable for sterilisation.

The use of inappropriate cleaning and detergent materials on medical equipment could damage surfaces and may compromise the ability to decontaminate medical devices adequately or may interfere with device function.

When the pump or mattress is no longer required dispose of the equipment in accordance with the local regulations. WEEE requirements do apply to the pump unit and any electrical components including cables which are used for or with this product.

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ROUTINE SERVICING

SERVICING YOUR SYSTEM

The Harvest 3 pump should be serviced every **12 months** by Harvest Healthcare approved personnel using genuine Harvest Healthcare spare parts.

Failure to follow the service schedule may invalidate future warranty claims (‘Guarantees & Warranties’ can be found on page 23).

TROUBLESHOOTING

FAULT	CHECK THAT	STAGE 2 CHECK	IF PROBLEM PERSISTS
Pump shows no indication that it is powered up.	1. Mains plug is plugged in and power switched on. 2. The power switch on the pump is switched on. 3. The fuse in the mains plug is not blown. 4. The wall socket that the pump is connected to is working correctly.	1. Connect the pump to the nearest (working) mains outlet. 2. Replace the plug fuse with the correct 5A fuse. 3. Try a different device in the mains outlet.	Contact Harvest Healthcare technical support. **Before calling:** Please ensure you have the serial number and model of equipment. Please record details of the results of the recommended tests. (Notes pages are provided at the back of this user manual).

FAULT	CHECK THAT	STAGE 2 CHECK	IF PROBLEM PERSISTS
The pump appears to be running but the mattress is not inflating correctly and or the low pressure light is illuminated.	**PLEASE NOTE** **Inflation can take up to 30 minutes.** 1. The hoses are routed correctly (not kinked) and connected to the pump correctly. 2. The CPR valve is not trapped and is in the closed position.	1. Disconnect and then re-connect the hoses to the outlet on the side of the pump. 2. Open then reclose the CPR valve, make sure the valve is not trapped in the bed mechanism.	Contact Harvest Healthcare technical support. **Before calling:** Please ensure you have the serial number and model of equipment. Please record details of the results of the recommended tests. (Notes pages are provided at the back of this user manual).
	1. There are no leaks in the mattress. 2. The tubes in the mattress are not disconnected or kinked.	1. Replace any damaged or leaking mattress parts with the correct genuine Harvest Healthcare spare parts. 2. Straighten out any kinked pipes and reconnect any disconnected joints.	

TROUBLESHOOTING

FAULT	CHECK THAT	STAGE 2 CHECK	IF PROBLEM PERSISTS
Some of the cells appear to be deflated.	This is normal for alternating pressure therapy. The mattress is made up of individual air cells. The alternating section is split up into 2 sections consisting of odd cells e.g. 1,3,5 etc and even cells e.g. 2,4,6 etc. These two sections will alternate through a 10 minute cycle in which time both sets of alternating air cells will have inflated and deflated sequentially.		
The system does not appear to be alternating.	1. **Check that the static mode is not turned on.** 2. Carefully mark one of the inflated cells with a pen. 3. Ensure that there are no kinks in the pipework down the side of the mattress. 4. Check the cycle time on the control panel. Recommended setting 10 minutes unless a health professional has recommended otherwise.	1. Monitor the cell for 7 minutes to see if it deflates. 2. Straighten out any kinked pipes.	Contact Harvest Healthcare technical support. **Before calling:** Please ensure you have the serial number and model of equipment. Please record details of the results of the recommended tests. (Notes pages are provided at the back of this user manual).

FAULT	CHECK THAT	STAGE 2 CHECK	IF PROBLEM PERSISTS
The pump is vibrating or making excessive noise.	The pump is fitted to the bed correctly.	Reposition the pump unit.	Contact Harvest Healthcare technical support. **Before calling:** Please ensure you have the serial number and model of equipment. Please record details of the results of the recommended tests. (Notes pages are provided at the back of this user manual).
The mattress is uncomfortable.	Check the comfort setting on the pump.	Set the pump to the correct setting using the guide on the front of the pump case.	

PARTS LIST

APPLIED PARTS

HPU3	Harvest 3 Pump (only)

REPLACEMENT PARTS

PU101	Compressor
PU102	Bellows
PU300	Connector
PU301	PCB Board
PU302	Front Panel Sticker
PU303	Case
PU304	Bed Hooks
UN012	Filter
PU305	Timer Motor

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GUARANTEES & WARRANTIES

PUMP

The pump is covered by warranty for a period of 3 years from the date of purchase. This excludes all serviceable parts such as the bellows and filters which are recommended to be changed every 12 months in line with the service schedule.

GUARANTEE

Harvest Healthcare Ltd guarantees to repair or replace all goods supplied to its customers which are found to be defective whilst still in their applicable warranty period. All warranties are subject to the following conditions:

A Warranty/guarantee is subject to all guidelines being adhered to.

B That the equipment has been used for the purpose for which it was intended.

C That the usage has been on a fair wear and tear basis. This does not include user damage.

D That Harvest Healthcare's cleaning/disinfecting guidelines have been followed.

E Harvest Healthcare's maintenance guidelines have been followed (please refer to the product manual).

F That ALL maintenance has been carried out by a suitably qualified and competent person.

G That all parts used are OEM (Original Equipment Manufacturer) parts and were supplied by Harvest Healthcare either directly or through a distributor.

H All warranties begin from the time the product leaves the premises of Harvest Healthcare.

I All repairs and replacements will be at the sole discretion of Harvest Healthcare.

Our standard terms and conditions of sale can be found on our website or by request to Harvest Healthcare.

If this device malfunctions and a serious incident occurs please contact Harvest Healthcare Ltd or your competent authority. A member of our service team will be happy to help you and offer advice.

Email: **servicing@harvesthealthcare.co.uk**
Telephone: **01709 377172**

DECLARATION OF CONFORMITY

DECLARATION OF CONFORMITY

Declaration of Conformity Annex VII EU Directive 93/42/EEC

We, as company: Harvest Healthcare Ltd
Sheaf House
Bradmarsh Way
Bradmarsh Business Park
Rotherham, S60 IBW

Authorised Representative: TBC
SRN: TBC

Confirm on our own behalf that the medical product:

Harvest Pump 3 - HPU3 - UDI: 5060517530174
Risk Class: IIa
SRN: TBC

complies with all applicable requirements in Appendix I of the EU directive 93/42E EC
The following compliance evaluation process was applied: Annex VII
EU legislation for this type of product covers all safety, health and environmental requirements.

Modifying this product without consultation with Harvest Healthcare Ltd will invalidate this declaration of conformity.

This declaration of conformity is issued under the sole responsibility of Harvest Healthcare.

Notified Body: TBC

Product Development and Quality Manager
Rotherham, 23.03.2020

This document is valid for 4 years after the date of the signature.

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Serial No:

DOCUMENT REFERENCE: HPU3- Harvest 3 Pump- March 2020

The pump is supplied by Harvest Healthcare Ltd and complies to the standard EN 60601-1.